IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAS) PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION**
	:	**MDL No. 3094**
	:	**2:24-md-3094-KSM**

MASTER LONG FORM COMPLAINT AND DEMAND FOR JURY TRIAL

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Plaintiffs' Co-Lead Counsel, on behalf of Plaintiffs, file this Master Long Form Complaint against the following currently named Defendants: NOVO NORDISK A/S, NOVO NORDISK INC.,[1] ELI LILLY AND COMPANY, and LILLY USA, LLC (collectively referred to as "Defendants") as an administrative method to set forth common facts and potential claims which individual Plaintiffs, on their own behalf, their spouses, estates, or beneficiaries, may assert against Defendants in this litigation. It is anticipated that Plaintiffs alleging personal injury and damages arising from the use of Defendants' prescription glucagon-like peptide-1 receptor agonist (GLP-1 RA) products (hereinafter, together or individually, "the GLP-1 RA Products" or "GLP-1 RAs") will file a Short Form Complaint,[2] and all allegations pleaded in this Master Long Form Complaint shall be deemed pleaded in any Short Form Complaint.

This Master Long Form Complaint sets forth questions of fact and law common to those claims subsumed within the context of this multidistrict proceeding. Plaintiffs seek compensatory and punitive damages, monetary restitution, and all other available remedies as a result of injuries caused by Defendants' defective pharmaceutical products and Defendants' actions. Plaintiffs make the following allegations based upon their personal knowledge, and upon information and belief, as well as upon their attorneys' investigative efforts, regarding Defendants' GLP-1 RA Products.

This Master Long Form Complaint does not necessarily include all claims asserted in all of the actions transferred to this Court, is not intended as the operative pleading for purposes of judgment and appeal, and is not intended to merge or consolidate, for any purpose, the separate

[1] *See* ECF 161, Stipulation Regarding Claims Against Certain Novo Defendants (filed June 28, 2024) (stipulating that Novo Nordisk Inc. and Novo Nordisk A/S "will not claim, assert, or acquiesce to the position that Other Novo Entities are a reasonable party or liable party in this action, and to the extent a jury were to place any percentage of responsibility on the Other Novo Entities, [Novo Nordisk Inc. and Novo Nordisk A/S] assumes that liability ... .").

[2] The template for a Short Form Complaint will be separately submitted to the Court.

claims of the Plaintiffs herein. Any separate facts and additional claims of individual Plaintiffs will be set forth in the Short Form Complaints filed by the respective Plaintiffs or their counsel. This Master Long Form Complaint does not constitute a waiver or dismissal of any actions or claims asserted in those individual actions, nor does any Plaintiff relinquish the right to move to amend their individual claims to assert any additional facts or seek any additional claims as discovery proceeds and facts and other circumstances may warrant.

INTRODUCTION

1. These are personal injury actions against the Defendants who were responsible for the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, labeling, sale and/or distribution of their GLP-1 RA Products, including but not limited to Ozempic, Wegovy, Rybelsus, Saxenda, Victoza, Mounjaro, Zepbound, and Trulicity.

2. Medications within the GLP-1 RA class of drugs are intended to mimic the activities of physiologic GLP-1, a gut hormone that binds to receptors throughout the body and, notably, activates GLP-1 receptors in the pancreas to stimulate the release of insulin and suppress glucagon.[3]

3. GLP-1 RAs are prescribed, for certain patient populations, to treat type 2 diabetes, aid in chronic weight management, and reduce cardiac risk.

4. Defendants have acknowledged that gastrointestinal events are well known side effects of the GLP-1 RA class of drugs.[4] However, Defendants have downplayed the nature, duration, extent and seriousness of gastrointestinal events and failed to warn about other adverse

[3] Hinnen, *Glucagon-Like Peptide 1 Receptor Agonists for Type 2 Diabetes*, 30(3), Diabetes Spectr. (Aug. 2017) available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5556578/.

[4] *See, e.g.*, CT Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell"*, Rolling Stone (July 25, 2023), available at https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601.

events caused by their GLP-1 RAs. Defendants have never provided adequate warnings about the risks of, among other things, debilitating cyclical vomiting for days and weeks requiring hospitalization, gastroparesis requiring emergent care or hospitalization, ileus, intestinal obstruction, gallbladder injury, Deep Vein Thrombosis (DVT), vitamin deficiency, Wernicke's Encephalopathy, ischemic bowel, necrotizing pancreatitis, all other injuries mentioned in this Master Complaint and their sequelae.

5. The decision to target the American population for the sale of Defendants' weight-loss drugs was not accidental. Defendants understood the vast financial potential of marketing a weight-loss medication in the United States where obesity rates were on the rise despite the culture's obsession with losing weight and being thin.

6. Defendants set on a course to create and expand the market for weight-loss medication by, among other things, advocating for obesity to be classified as a disease and thereby expanding the market for their drugs, spending hundreds of millions of dollars in an effort to change the medical consensus on how to treat that disease, implementing cutting-edge invasive, unprecedented and multifaceted marketing campaigns that were so effective they engrained these drugs in the pop culture zeitgeist, and spending untold millions in an effort to get weight-loss medications covered under public and private insurance. Defendants engaged in this conduct even before GLP-1 RAs were approved for weight-loss, encouraging extensive off-label demand and use.

7. By undertaking that effort, Defendants also were systematically and intentionally targeting users of other diabetes medications. Defendants' promise of weight loss wrongfully enticed users of other diabetes medications to switch to a GLP-1 RA who never would have done so had it not been for the off-label promotion of those drugs.

8. Defendants also sought to make the GLP-1 RAs more accessible by, among other things, marketing through telemedicine where the criteria for qualifying for the drugs, *e.g.*, Body Mass Index ("BMI"), are more easily manipulated.

9. Defendants' efforts to conceal (or minimize) the risks associated with taking their drugs were intended to create the impression that these were "magic pills" to help a person lose weight. However, Defendants never disclosed that many people who take these drugs stop taking them because of the drastic side effects (thereby never achieving weight loss or any health benefit allegedly associated with the drug); the drugs do not result in meaningful weight loss for up to 15% of people;[5] the average weight loss for someone taking the drugs is a modest 10.09% of the person's body weight;[6] and that a person will need to stay on these drugs for the rest of their lives to maintain the weight loss.[7] What is worse is that Defendants kept this information hidden while actively degrading trust in the prevailing view that lifestyle changes like proper nutrition and exercise were the keys to health and can accomplish long-lasting weight-loss and management for most people.

10. The efforts to engrain GLP-1 RAs such as Ozempic in the public conscious, to manipulate the medical community's views on obesity treatment, and to make the drugs more

[5] Carbajal, Erica, *Up to 15% of patients on weight loss drugs may be 'non-responders'*, Becker's Hospital Review (April 1, 2024) available at https://www.beckershospitalreview.com/glp-1s/up-to-15-of-patients-on-weight-loss-drugs-non-responders.html.

[6] Gao, *et al*., *Efficacy and safety of semaglutide on weight loss in obese or overweight patients without diabetes: A systematic review and meta-analysis of randomized controlled trials*, Frontiers in Pharmacology 1 (2022).

[7] Wilding, *et al*., *Weight regain and cardiometabolic effects after withdrawal of semaglutide: The STEP 1 trial extension*, 24 Diabetes Obes Metab. 1553, 1562 ("[T]reatment withdrawal led to most of the weight loss being regained within 1 year, …, reinforcing the need for continued treatment to maintain weight loss ….").

accessible acted as a launching pad for the explosive growth of the GLP-1 RAs both for people who were diabetics, and for people seeking to lose weight, whether they were using the drug as prescribed or off-label. Plaintiffs would not have taken GLP-1 RAs if they had been provided a full and clear warning of the true risks of taking these drugs.

11. Defendants' efforts to expand and grow the market both for treatment of diabetes and weight-loss, whether off-label or not, worked. The U.S. GLP-1 RA market is expected to exceed $100 Billion by 2030 with total U.S. users comprising about 9% of the population.[8] This growth is a tremendous boon to Defendants but comes at a significant cost. Financially, it is expected that Defendants' lobbying efforts will pay off, and GLP-1 RAs may get added to prescription drug coverage under Medicare Part D in the coming years. Some analysts project that this will add $13.6 to $26.8 Billion to Medicare Part D expenses even if only 10% of people with obesity use them, causing a significant shift in premiums and coverage in other areas.[9]

12. The outsized growth of the market for GLP-1 RAs also means that the patient base has expanded to include many patients who would be better served choosing alternate treatment paths. Defendants' marketing campaigns have altered the public understanding of weight loss treatment, creating the impression that GLP-1 RAs are not just one tool among many available to doctors, but are instead "miracle drugs." But, these patients, like Plaintiffs, were lured into a false sense of hope that GLP-1 RAs would guarantee results and be efficacious and safe. Plaintiffs injected themselves with GLP-1 RAs believing that they were doing something to promote their health when, in fact, it had the opposite effect.

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[8] J.P. Morgan Research, *The increase in appetite for obesity drugs* (Nov. 29, 2023), available at https://www.jpmorgan.com/insights/global-research/current-events/obesity-drugs#section-header#0.

[9] https://www.vumc.org/health-policy/medicare-antiobesity-medications-nejm.

13. As a result of the foregoing, Plaintiffs have suffered and were diagnosed with various forms of injury which were directly and proximately caused by their regular and prolonged use of GLP-1 RAs. Plaintiff's injuries include, but are not limited to: gastroparesis, ileus, intestinal obstruction, ischemic bowel, gallbladder injury, DVT, and their sequelae, including debilitating nausea, debilitating vomiting, debilitating diarrhea, debilitating abdominal pain, debilitating gastrointestinal burning, debilitating bloating, extreme constipation, dangerous life threatening dehydration, micronutrient deficiencies, gallbladder removal, high blood pressure, and emotional distress, as well as other injuries set forth herein or to be set forth in a Short Form Complaint, Plaintiff Fact Sheet, or other responsive discovery.

THE PARTIES

14. This Master Long Form Complaint is filed on behalf of all Plaintiffs and, if applicable, Plaintiffs' spouses, children, descendants, estates, wards, executors, administrators, guardians, conservators, or other representatives who file a Short Form Complaint. Allegations pleaded herein are incorporated into any Short Form Complaint filed in this MDL.

15. Defendant Novo Nordisk A/S is and at all relevant times has been a public limited liability company organized under the laws of Denmark with a principal place of business in Bagsværd, Denmark.

16. Defendant Novo Nordisk Inc. is and at all relevant times has been a Delaware corporation with a principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey.

17. Defendants Novo Nordisk Inc., and Novo Nordisk are referred to collectively herein as "the Novo Nordisk Defendants" or "Novo Nordisk" or "Novo."[10]

18. Each of the Novo Nordisk Defendants was the agent and employee of the other

[10] All Novo-related entities are included in these terms. *See* ECF 161; Note 1, *supra*.

Novo Nordisk Defendants and, in doing the things alleged, was acting within the course and scope of such agency and employment and with the other Novo Nordisk Defendants' actual and implied permission, consent, authorization and approval.

19. In collaboration amongst themselves, as part of their business, and at all relevant times, the Novo Nordisk Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed GLP-1 RAs, including Ozempic, Rybelsus, Wegovy, Victoza, and Saxenda.

20. Defendant Eli Lilly and Company is and at all relevant times has been an Indiana corporation with a principal place of business at 893 S. Delaware St., Indianapolis, Indiana.

21. Defendant Lilly USA, LLC is and at all relevant times has been an Indiana LLC with a principal place of business at 893 S. Delaware St., Indianapolis, Indiana.

22. Defendants Eli Lilly and Company and Lilly USA, LLC are referred to collectively herein as "the Eli Lilly Defendants" or "Eli Lilly" or "Lilly."

23. Each of the Eli Lilly Defendants was the agent and employee of the other Eli Lilly Defendants and, in doing the things alleged, was acting within the course and scope of such agency and employment and with the other Eli Lilly Defendants' actual and implied permission, consent, authorization and approval.

24. In collaboration amongst themselves, as part of their business, and at all relevant times, the Eli Lilly Defendants designed, researched, manufactured, tested, labeled, advertised, promoted, marketed, sold, and/or distributed GLP-1 RAs, including Trulicity, Mounjaro, and Zepbound.

JURISDICTION AND VENUE

25. This Court has original jurisdiction over each individual action pursuant to 28 U.S.C. § 1332(d) because the amount in controversy alleged in each of the respective individual

actions will exceed the sum or value of $75,000.00, exclusive of interest and costs, and complete diversity of citizenship exists between each Plaintiff and each Defendant, as well as for any other reason identified in a Short Form Complaint.

26. Defendants have significant contacts with Pennsylvania (where general jurisdiction exists over any of the Defendants that have registered to do business in the Commonwealth),[11] the Eastern District of Pennsylvania and each of the federal judicial districts identified in each Short Form Complaint such that they are subject to the personal jurisdiction of the Court, as well as the courts in each transferor district.

27. Defendants are each and at all relevant times have been multinational Fortune 500 companies that have significant contacts in each of the States and Territories of the United States, such that personal jurisdiction would be proper in any of them. Defendants have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and Defendants have derived substantial revenue from the sale of their respective GLP-1 RAs in each of the States and Territories of the United States.

28. Pursuant to 28 U.S.C. § 1391(a), venue is proper in the federal judicial district identified in any Short Form Complaint because substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in there, or for any other reason identified in the Short Form Complaint; and venue is also proper in this District on account of the MDL designation pursuant to 28 U.S.C. § 1407.

[11] *See Mallory v. Norfolk Southern Ry. Co.*, 600 U.S. 122 (2023).

FACTUAL ALLEGATIONS

A. INTRODUCTION TO GLP-1 AND GLP-1 RA PRODUCTS

29. Researchers first discovered GLP-1 in hamsters in 1983.[12] It is a hormone that helps regulate blood sugar, appetite, and digestion in animals, including humans; and is produced naturally in the brain and intestinal wall of humans.

30. In 1993, researchers discovered that a peptide from the venom of gila monsters activated GLP-1 receptors.[13] Gila monsters can go for months without eating but maintain stable blood sugar levels because they make very high levels of a glucagon peptide called exendin-4. Thus, the gila monster served as the inspiration for the GLP-1 RA class of drugs.

31. Following the discovery that exendin-4 is similar in structure to GLP-1, a synthetic version of exendin-4 was developed to treat diabetes. This became the first GLP-1 drug, known as Byetta, with the active ingredient exenatide, which came to market in 2005. Byetta was initially brought to market as a collaboration between Lilly and Amylin.[14] Whereas naturally-occurring GLP-1 has a short half-life of just a few minutes, Byetta's half-life was noted to be 2.4 hours.[15]

32. Simultaneously with the development of exenatide, Novo was developing another GLP-1 drug called liraglutide. In the early 1990s, Novo researchers discovered that when they

[12] Bell et al., *Hamster preproglucagon contains the sequence of glucagon and two related peptides*, 302 Nature 716 (1983).

[13] Thorens et al., *Cloning and functional expression of the human islet glp-1 receptor*, 42 Diabetes 1678 (1993).

[14] News Release: Amylin and Lilly Announce FDA Approval of BYETTA(TM) (Exenatide Injection) (Apr. 29, 2005), *available at* https://investor.lilly.com/news-releases/news-release-details/amylin-and-lilly-announce-fda-approval-byettatm-exenatide (last visited Nov. 8, 2023) (describing the drug as a "collaboration" between Amylin and Lilly).

[15] Cai, et al., *Long-acting preparations of exenatide*, Drug Des. Devel. Ther. (Sept. 2013).

injected liraglutide into rats, it caused them to stop eating almost entirely.[16] Liraglutide came to market in 2010, marketed initially as Victoza and later as Saxenda. Liraglutide has a half-life of 13-15 hours.[17]

33. Various active ingredients fall within the GLP-1 RA class of drugs, including semaglutide (marketed by Novo as Ozempic, Wegovy, and Rybelsus), liraglutide (marketed by Novo as Saxenda, Victoza, and in combination with insulin as Xultophy 100/3.6), tirzepatide (marketed by Lilly as Mounjaro and Zepbound), dulaglutide (marketed by Lilly as Trulicity), exenatide (marketed by various companies as Byetta, Bydureon, and Bydureon BCise), albiglutide (marketed by GlaxoSmithKline as Tanzeum), and lixisenatide (marketed by Sanofi as Adlyxin and in combination with insulin as Soliqua 100/33).

34. GLP-1 RAs are recognized by the U.S. Food & Drug Administration ("FDA") to constitute a "class" of drugs based on similarities in their mechanisms of action, physiologic effects, and chemical structure.[18] Defendants likewise recognize that their GLP-1 RAs are members of the same class.[19]

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[16] Gina Kolata, *We Know Where New Weight Loss Drugs Came From, but Not Why They Work*, New York Times (Aug. 17, 2023), available at https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html.

[17] Rubino, *et al*., *Effect of Weekly Subcutaneous Semaglutide vs Daily Liraglutide on Body Weight in Adults with Overweight or Obesity without Diabetes: The STEP 8 Randomized Clinical Trial*, JAMA (Jan. 2022).

[18] *See* FDA Ozempic Summary Review https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209637Orig1s000SumR.pdf (including liraglutide, dulaglutide, and semaglutide in the GLP-1 RA class) (last visited Dec. 28, 2023); *see also* FDA Mounjaro Clinical Review https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/215866Orig1s000MedR.pdf at 52 (results of tirzepatide toxicology studies in animals were typical of the GLP-1 RA pharmacologic class) (last visited Dec. 28, 2023); *see also* https://www.fda.gov/industry/structured-productlabeling-resources/pharmacologic-class (last visited Dec. 28, 2023).

[19] SURMOUNT-1 Clinical Trial Protocol at 45, available at https://cdn.clinicaltrials.gov/large-docs/22/NCT04184622/Prot_000.pdf ("General safety characteristics of all studied doses of

35. Medications within the GLP-1 RA class of drugs mimic the activities of physiologic GLP-1 in numerous ways,[20] including attaching to GLP-1 receptors, sending various signals in the body, triggering a sensation of satiety (or perception of fullness, thereby curbing users' appetites and decreasing intake of calories and nutrients),[21] acting on the pancreas to stimulate the release of insulin, suppressing the release of glucagon, and slowing or inhibiting gastric emptying and intestinal motility.[22]

36. In contrast to naturally-occurring GLP-1, which has a short life and is quickly metabolized by enzymes, GLP-1 RAs are engineered to last longer, as previously noted. The chemical structure of GLP-1 RAs includes a fatty chain that inhibits such quick dissolution. GLP-1 RAs such as semaglutide and tirzepatide have a long half-life of well over 100 hours, causing the drugs to stay in the body for a month or more after the last dose.

37. Most GLP-1 RAs are approved to treat type 2 diabetes,[23] but some (Wegovy,

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tirzepatide were similar to those of the GLP-1R agonist class…"); STEP-1 Clinical Trial Protocol at 15, accessible at https://cdn.clinicaltrials.gov/large-docs/35/NCT03548935/Prot_002.pdf ("[T]he tolerability and safety profile [of semaglutide] was overall consistent with… the GLP-1 RA class in general.").

[20] Cleveland Clinic, *GLP-1 Agonists* (July 3, 2023), available at https://my.clevelandclinic.org/health/treatments/13901-glp-1-agonists.

[21] *See* Bloemendaal, *et al*., *Effects of glucagon-like peptide 1 on appetite and body weight: focus on the CNS*, J. Endocrinology (Apr. 2014).

[22] Deane, *et al*., *Endogenous Glucagon-Like Peptide-1 Slows Gastric Emptying in Healthy Subjects, Attenuating Postprandial Glycemia*, 95(1) J Clinical Endo Metabolism, 225-221 (January 1, 2010), available at https://academic.oup.com/jcem/article/95/1/215/2835243 (last visited 9/26/23); American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 29, 2023), available at https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery.

[23] Unlike patients with type 1 diabetes, who cannot produce insulin, patients with type 2 diabetes cannot use insulin properly. *Compare* Cleveland Clinic, *Type 1 Diabetes* (March 9, 2022), available at https://my.clevelandclinic.org/health/diseases/21500-type-1-diabetes (last visited 10/3/24) *with* Cleveland Clinic, *Type 2 Diabetes* (Nov. 8, 2023), available at

Saxenda, and Zepbound) are approved to treat obesity or to reduce cardiovascular risks.

38. Most GLP-1 RAs are administered by injection, with the exception of Rybelsus, which is in tablet form.[24]

39. Most of the GLP-1 RAs at issue in this case are weekly injectable drugs, except that liraglutide (the active ingredient in Saxenda and Victoza) is a daily injectable drug.[25]

40. Most GLP-1 RAs are dosed between 0.25 and 2 milligrams per week, except that the maximum dose for Wegovy is 2.4 milligrams per week, and the maximum dose for Mounjaro is 15 milligrams per week.

B. INTRODUCTION TO PLAINTIFFS' INJURIES

41. GLP-1 RAs can cause a myriad of injuries including: developing gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; ischemic bowel, DVT and associated pulmonary embolism ("PE"); gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; muscle wasting; vitamin deficiencies, including micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis.

42. These injuries can be debilitating and go so far as to result in death. The FDA adverse events database lists nearly 500 deaths related to semaglutide (Novo's GLP-1 RA) in the

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https://my.clevelandclinic.org/health/diseases/21501-type-2-diabetes.

[24] Cleveland Clinic, *GLP-1 Agonists* (July 3, 2023), available at https://my.clevelandclinic.org/health/treatments/13901-glp-1-agonists.

[25] *Id*.

United States.[26] Recent reports indicate that a British nurse, Susan McGowan, aged 58, passed away from "multiple organ failure, septic shock . . . pancreatitis . . . and "the use of prescribed tirzepatide" (Lilly's GLP-1 RA).[27] In the United Kingdom, there have been at least 23 deaths linked to semaglutide since 2019.[28]

1. Gastrointestinal Injuries

43. Gastrointestinal adverse events are well known side effects of the GLP-1 RA class of drugs, as Defendants have acknowledged,[29] but Defendants have downplayed the chronic nature, duration and severity of gastrointestinal injuries caused by their GLP-1 RAs. Many Plaintiffs in this case have experienced debilitating, long-lasting effects, such as vomiting week after week (i.e., unremitting or cyclical vomiting), and for many Plaintiffs, even after being hospitalized and discharged, the effects of life-altering treatment, such as replacement of their colon with a colostomy bag[30], persist. In addition, many Plaintiffs have experienced adverse events for which Defendants failed to provide any warning.

44. These gastrointestinal injuries caused by GLP-1 RAs can lead to life threatening and long-term consequences, including hospitalization, esophageal tearing, ischemia and necrosis

[26] https://www.cnn.com/2024/11/06/health/compounded-semaglutide-deaths-novo-nordisk-ceo/index.html (last visited 11/10/2024).

[27] MacPhee and Cheyne, *Nurse's death linked to approved weight-loss drug*, https://www.bbc.com/news/articles/cz6jg6nw2zeo (last visited 11/10/2024).

[28] *Id*.

[29] *See, e.g.*, Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell"*, Rolling Stone (July 25, 2023), available at https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601.

[30] A colostomy bag collects stool. It is attached to the body through a surgical procedure called a colostomy that changes the way that stool exits the body. When medical reasons (such as a removal of part of the bowel) require the colon to be bypassed, surgeons make a new opening in the abdominal wall for stool to come out.

in the digestive tract, bowel perforation, sepsis, bowel resection, colostomy, perioperative aspiration, dehydration, micronutrient deficiency, disability, and death.

a. Gastroparesis

45. Gastroparesis is the slowing or halting of transit of food from the stomach to the intestines in the absence of a physical obstruction. Common symptoms of gastroparesis include nausea, vomiting, abdominal bloating, early satiety, and abdominal pain or discomfort. Moderate cases of gastroparesis often require acute or emergency care and treatment while more debilitating cases of gastroparesis can require hospitalization.[31] During normal gastric emptying, food passes quickly from the stomach. Muscles surrounding the stomach contract to move solid food through the pyloric sphincter and out of the stomach. However, with gastroparesis, the digestive muscles surrounding the stomach move more slowly and weakly and the pyloric sphincter remains closed, causing solid food to remain in the stomach for extended periods.[32] Gastroparesis can interfere with normal digestion and cause nausea, vomiting (including vomiting of undigested food), abdominal pain, abdominal bloating, severe dehydration, a feeling of fullness after eating just a few bites, undigested food hardening and remaining in the stomach, acid reflux, changes in blood sugar levels, lack of appetite, weight loss, and a decreased quality of life.

46. GLP-1 RA-induced gastroparesis is persistent, and for many Plaintiffs, symptoms continue for weeks following cessation of GLP-1 RAs. In some cases, gastroparesis leads to secondary conditions which may never resolve, such as Wernicke's encephalopathy.

47. There are no good treatments for gastroparesis. Treatment often depends upon the severity of the symptoms. While many cases of gastroparesis require correcting fluid, electrolyte,

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[31] Henry P. Parkman, *American Gastroenterological Association Technical Review on the Diagnosis and Treatment of Gastroparesis*, Gastroenterology (Nov. 2004).

[32] *See id.*

and nutritional deficiencies, reducing symptoms, and identifying the underlying cause; other cases require treatment with the drug Metoclopramide. Metoclopramide is the only medicine the FDA has approved for the treatment of gastroparesis. The Metoclopramide pill has a risk of serious side effects.

48. The most serious cases of gastroparesis may leave patients unable to have any food or liquids. These individuals may require a feeding tube called a jejunostomy to be placed in the small intestines, or a gastric venting tube to be inserted to help relieve pressure from gastric contents.

49. Gastric electrical stimulation is another tool for the treatment of gastroparesis. In gastric electrical stimulation, a device is implanted into the body to provide electrical stimulation to the stomach muscles to improve gastric motility.

50. In a 2004 review of gastroparesis published by the American Gastroenterological Association, the authors recommended that treating physicians should review the medications of patients experiencing gastroparesis in order to "eliminate drugs that might exacerbate the underlying dysmotility disorder. . . ."[33] Thus, it is important for clinicians to know whether a drug can induce or contribute to gastroparesis.

51. Treatment of more debilitating gastroparesis can include the prescription of medications with serious side effects.

52. When gastroparesis does not resolve after cessation of GLP-1 RAs, further treatment options are limited and undesirable, with each carrying its own significant risks. The only medicine approved by the FDA to treat gastroparesis, metoclopramide, has risks of serious

[33] *See id.*

side effects,[34] including a permanent movement disorder called tardive dyskinesia, and is recommended only for short term use of 12 weeks or less.[35] For patients whose gastroparesis is debilitating enough to prevent them from consuming food or liquids, a feeding tube called a jejunostomy tube placed in the small intestine, or a gastric venting tube to help relieve pressure from gastric contents, may be necessary.[36]

b. Ileus

53. Ileus is "a temporary lack of the normal muscle contractions of the intestines."[37] Muscles in the intestines normally contract and relax, causing a wave-like motion called peristalsis, which moves food through the intestines. When ileus occurs, this peristalsis is slowed or stopped, preventing food, gas, and liquids from passing through the digestive tract. This causes pain, cramps, abdominal bloating, nausea, vomiting, severe constipation, and loss of appetite. When a person suffering from ileus eats solid food, a backlog of food particles may cause a partial or total obstruction of the intestines.[38]

54. Paralytic ileus, also known as a pseudo-obstruction, is the most severe form of ileus and occurs when nerves in the intestinal walls do not work as they should, and peristalsis is temporarily paralyzed. Paralytic ileus is a functional problem in which the muscles and nerves

[34] Mayo Clinic, *Gastroparesis* (Sept. 6, 2024), available at https://www.mayoclinic.org/diseases-conditions/gastroparesis/diagnosis-treatment/drc-20355792.

[35] Mayo Clinic, *Metoclopramide (oral route)* (Feb. 1, 2024), available at https://www.mayoclinic.org/drugs-supplements/metoclopramide-oral-route/description/drg-20064784.

[36] Mayo Clinic, *Gastroparesis* (Sept. 6, 2024), available at https://www.mayoclinic.org/diseases-conditions/gastroparesis/diagnosis-treatment/drc-20355792.

[37] Parswa Ansari, *Ileus*, Merck Manual (April 2023), available at https://www.merckmanuals.com/home/digestive-disorders/gastrointestinal-emergencies/.

[38] Jayne Leonard, Youssef (Joe) Soliman, *What is Ileus?*, Medical News Today (March 13, 2023), available at https://www.medicalnewstoday.com/articles/322149.

mimic an intestinal obstruction, even when there is no mechanical obstruction in the intestines; this causes food to be trapped in the intestines.[39]

55. Intestinal obstruction (also known as bowel obstruction), which may also arise from ileus, refers to a partial or total blockage of the intestine, preventing food, liquids or gas from passing through.[40] This may cause the intestine to rupture, leaking harmful contents into the abdominal cavity, or "the blocked parts of the intestine can die, leading to serious problems."[41] Similar to ileus, symptoms of intestinal obstruction include cramps, abdominal pain, loss of appetite, constipation, vomiting, inability to have a bowel movement or pass gas, and swelling of the abdomen.[42] Unlike ileus, which refers to the slowing or stopping of peristalsis, generally from muscle or nerve problems, intestinal obstruction refers to the physical blockage of the digestive tract.[43]

c. Other Gastrointestinal Injuries

56. While many injured by Defendants' GLP- 1 RAs are formally diagnosed with gastroparesis, many others experience serious injuries caused by the delays of gastric emptying.

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[39] Cleveland Clinic, *Paralytic Ileus* (Oct. 8, 2021), available at https://my.clevelandclinic.org/health/diseases/21853-paralytic-ileus (last visited 10/16/23); *see also* Mayo Clinic, Intestinal Obstruction, available at https://www.mayoclinic.org/diseases-conditions/intestinal-obstruction/diagnosis-treatment/drc-20351465?p=1.

[40] Kristeen Moore, E. Mimi Arquilla, *Bowel Obstruction and Blockage*, Healthline (March 15, 2023), available at https://www.healthline.com/health/intestinal-obstruction (last visited 10/16/23).

[41] Mayo Clinic, Intestinal Obstruction, available at https://www.mayoclinic.org/diseases-conditions/intestinal-obstruction/symptoms-causes/syc-20351460 (last visited 10/16/23); *see also* Kristeen Moore, E. Mimi Arquilla, *Bowel Obstruction and Blockage*, Healthline (March 15, 2023), available at https://www.healthline.com/health/intestinal-obstruction.

[42] Mayo Clinic, Intestinal Obstruction, available at https://www.mayoclinic.org/diseases-conditions/intestinal-obstruction/symptoms-causes/syc-20351460 (last visited 10/16/23).

[43] Jayne Leonard, Youssef (Joe) Soliman, *What is Ileus?*, Medical News Today (March 13, 2023), available at https://www.medicalnewstoday.com/articles/322149.

These injuries include debilitating cyclical vomiting that can last days or weeks after cessation of the GLP-1 RAs, gastroenteritis,[44] esophageal tear, and intestinal obstruction associated with GLP-1 RAs.[45]

57. At least 20% of individuals on GLP-1 RAs experience gastrointestinal adverse effects; predominantly nausea, vomiting, and altered bowel function.[46]

58. Gastroenteritis refers to inflammation of the stomach and intestines. While viral gastroenteritis is also known as stomach flu, gastroenteritis may also be caused by ingesting medications. Its symptoms include debilitating vomiting, nausea, diarrhea, stomach cramps, muscle aches, headaches, and fever. Notably, vomiting and diarrhea can cause dehydration, which is the main complication of gastroenteritis, and which can lead to death.[47]

59. Patients on GLP-1 RAs can experience vomiting so severe they suffer a torn esophagus.[48]

2. Ischemic Bowel

60. Ischemic colitis, also known as ischemic bowel or bowel ischemia, is a condition that occurs when blood flow to the colon or large intestine is diminished. This can cause the death

[44] https://www.merckmanuals.com/home/digestive-disorders/gastroenteritis/drug-related-gastroenteritis-and-chemical-related-gastroenteritis (last visited 11/10/2024).

[45] Gudin, *et al*., *Incretin-based drugs and intestinal obstruction: a pharmacovigilance study*, 75(6) Therapies 641-47 (November-December 2020).

[46] Jalleh, *et al*., *Gastrointestinal effects of GLP-1 receptor agonists:mechanisms, management, and future directions* (Published online July 31, 2024) available at: https://doi.org/10.1016/S2468-1253(24)00188-2.

[47] https://www.mayoclinic.org/diseases-conditions/viral-gastroenteritis/symptoms-causes/syc-20378847 (last visited 11/10/2024); https://www.merckmanuals.com/home/digestive-disorders/gastroenteritis/drug-related-gastroenteritis-andchemical-related-gastroenteritis (last visited 11/10/2024).

[48] https://www.dailymail.co.uk/health/article-13087635/woman-torn-esophagus-ozempic-lawsuit-novo-nordisk.html.

of tissue in the affected area. Ischemic colitis can cause symptoms including abdominal pain, nausea, diarrhea, and blood in stool. Ischemic colitis can lead to obstruction or perforation of the bowel, and necrosis and infection of the affected tissue.[49]

61. Bowel obstruction and ischemic colitis can both be caused by fecal impaction due to chronic constipation.[50]

62. An October 2022 article in the American Journal of Gastroenterology reported a case in which a patient taking semaglutide was hospitalized for blood in her stool, tenesmus, and abdominal pain. Gastrointestinal pathology results were "suggestive of ischemic colitis," and after an MRI identified a portal vein thrombus, she had a coagulopathy workup which "suggest[ed] the clot was a manifestation of colonic ischemia." This article also mentioned that "multiple potential mechanisms [by which GLP-1RAs could cause ischemic colitis] exist including periods of hypotension due to decreased food and water intake. Further, delayed gastric emptying is a known feature of GLP-1-RAs and can be a manifestation of decreased gastric vascular supply."[51]

63. An October 2023 article in the Journal of the Endocrine Society reported a case in which a patient taking liraglutide developed a transient intussusception, a condition in which "one segment of the bowel telescopes into the adjacent segment, potentially causing intestinal

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[49] *Ischemic Colitis*, Mayo Clinic (last updated October 22, 2022), available at https://www.mayoclinic.org/diseases-conditions/ischemic-colitis/symptoms-causes/syc-20374001 (visited on 4/17/2024).

[50] *See, e.g.*, Szemein Gan, et al., *A case of colonic obstruction combined with ischemic colitis*, 4(1) AGING MED. 58 (published online January 20, 2021), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7954835/ (visited on 4/18/2024).

[51] Thomas A. Wichelmann, et al., Glucagon-Like Peptide-1 Receptor Agonist-Associated Colonic Ischemia: A Case Report, 117(10S) AM. J. GASTROENTEROLOGY 1424 (October 2022), available at https://journals.lww.com/ajg/fulltext/2022/10002/s2088_glucagon_like_peptide_1_receptor.2088.aspx (visited 4/18/2024).

ischemia." The article also noted that "Small bowel obstruction (SBO), though not well described in clinical trials, has been reported in observational studies [of GLP-1RAs]."[52]

64. The FDA's Adverse Events Reporting System (FAERS) shows multiple reports of "Intestinal Ischaemia" reported in connection with use of GLP-1RAs, including reports associated specifically with semaglutide. The earliest reported Intestinal Ischaemia event associated with any GLP-1RA occurred in 2007.[53]

65. Ischemic colitis' sequelae includes but is not limited to, abdominal pain, nausea, vomiting, decreased bowel function, sepsis, a syncopal episode and necrosis of the colon.

3. Necrotizing Pancreatitis

66. Necrotizing pancreatitis is a condition in which the pancreas becomes so severely inflamed that a portion of the pancreatic tissue dies (necrosis). Necrotizing pancreatitis can lead to complications including infection, sepsis, hemorrhage, accumulation of fluid in the abdomen, long-term pancreatic insufficiency, scarring of the pancreatic duct, bile ducts, and duodenum, and thrombosis (clotting) of nearby blood vessels.[54] Necrotizing pancreatitis is a condition "with high mortality."[55]

67. In 2012, a fatal case of acute necrotizing pancreatitis was reported in a patient

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[52] Sura Alqaisi, *et al*., *GLP-1RA Therapy And Intussusception: A Case Report Of Bowel Telescoping In An Obese Patient After Successful Weight Loss On Therapy*, 7 J. ENDOCR. SOC. Suppl. 1 (published online October 5, 2023), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10554870/.

[53] The FAERS database is accessible online at https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard.

[54] *Necrotizing Pancreatitis*, Cleveland Clinic (last updated December 11, 2023), available at https://my.clevelandclinic.org/health/diseases/necrotizing-pancreatitis.

[55] Leonard-Murali, *et al*., *Necrotizing pancreatitis: A review for the acute care surgeon*. Volume 221, Am J Surg. 927 (May 2021), available online at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8650167/.

taking exenatide (a GLP-1RA) in combination with Sitagliptin.[56]

68. In 2021, a severe case of acute necrotizing pancreatitis was reported in a patient taking dulaglutide (a GLP-1RA).[57]

69. The FDA's Adverse Events Reporting System (FAERS) shows numerous reports of "Pancreatitis Necrotizing" as a reaction to GLP-1RAs, including semaglutide.[58]

4. Gallbladder Disease

70. GLP-1 RAs pose a significant risk of biliary disease (diseases of the bile tract), specifically gallbladder-related complications, including cholelithiasis (gallstones), cholecystitis (inflammation of the gallbladder), and the need for cholecystectomy (gallbladder removal surgery).[59]

71. Cholelithiasis, commonly referred to as gallstones, involves the formation of solid particles within the gallbladder due to the crystallization of bile. GLP-1 RA have been shown to impair gallbladder motility, leading to bile stasis, where bile is not expelled efficiently from the gallbladder. This stasis promotes the development of gallstones. Patients using these drugs are at

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[56] Iyer, *et al*., *Case Report of Acute Necrotizing Pancreatitis Associated with Combination Treatment of Sitagliptin and Exenatide*, 18 ENDOCRINE PRACTICE E10 (2012), available at https://www.endocrinepractice.org/article/S1530-891X(20)40907-3/abstract#articleInformation (visited 4/8/2024).

[57] Bhat and Goudarzi, *Necrotizing Pancreatitis Secondary to Dulaglutide Use*, 5 J. ENDOCRINE SOC. A393 (May 2021), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8089879/.

[58] The FAERS database is accessible online at https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard. Case IDs for reports of necrotizing pancreatitis in patients taking Ozempic specifically, and dated prior to or concurrent with Plaintiff's use of Ozempic include 16858785, 19087469, 19576028, 19620306, and 20949233.

[59] Faillie, *et al*., *Association of Bile Duct and Gallbladder Diseases with the Use of Incretin-Based Drugs in Patients with Type 2 Diabetes Mellitus*, 176 JAMA Internal Med. 1474 (2016) at 12.

a higher risk of developing gallstones, which can cause significant pain and lead to further complications, such as cholecystitis or infection.[60]

72. Cholecystitis, the inflammation of the gallbladder, typically arises from gallstones obstructing the bile ducts. This condition can lead to debilitating abdominal pain, fever, infection, and other complications.[61] Cholecystitis often requires urgent medical intervention, including cholecystectomy (gallbladder removal surgery), to prevent further, dangerous complications.

73. Biliary sludge, a mixture of microscopic particles suspended in bile, can accumulate in the gallbladder and is often a precursor to more serious conditions such as gallstones or biliary obstruction. The impaired gallbladder motility caused by GLP-1 RAs can contribute to the buildup of biliary sludge.[62] This sludge can lead to inflammation and, if untreated, may cause significant damage to the biliary system, ultimately increasing the risk of gallbladder removal surgery.[63]

74. Biliary obstruction occurs when the bile ducts become blocked, preventing the flow of bile from the liver to the intestines. This condition is often caused by gallstones or biliary sludge obstructing the ducts, leading to debilitating pain, jaundice, and infection. GLP-1 RAs have been associated with an increased risk of biliary obstruction: clinical studies report a higher incidence of biliary-related complications in patients using these drugs.[64] Biliary obstruction can lead to

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[60] He, *et al*., *Association of Glucagon-Like Peptide-1 Receptor Agonist Use with Risk of Gallbladder and Biliary Diseases: A Systematic Review and Meta-analysis of Randomized Clinical Trials*, 182 JAMA Internal Med. 513 (2022) at 2; Yang, *et al*., *Weight Reduction and the Risk of Gallbladder and Biliary Disease: A Systematic Review and Meta-analysis of Randomized Clinical Trials*, 25 Obesity Rev. e13725 (2024) at 8.

[61] Nauck, *et al*., *Effects of Liraglutide Compared with Placebo on Events of Acute Gallbladder or Biliary Disease in Patients with Type 2 Diabetes at High Risk for Cardiovascular Events in the LEADER Randomized Trial*, 42 Diabetes Care 1912 (2019) at 1912-13, 1915.

[62] *Id.* at 1918.

[63] *See id.*

[64] *See generally*, He, *et al*., *Association of Glucagon-Like Peptide-1 Receptor Agonist Use with*

debilitating complications, including the need for medical intervention to restore bile flow. Studies have demonstrated that GLP-1 receptor agonists are associated with an increased risk of biliary and gallbladder diseases, which may require surgical procedures such as cholecystectomy in cases where these conditions progress.[65]

75. Patients who develop gallbladder or biliary complications as a result of using GLP-1 RAs often require medical or surgical interventions to prevent further damage and restore proper gallbladder or biliary function. These interventions range from non-invasive medical management to surgical procedures, depending on the severity of the condition.

76. For patients experiencing gallstones (cholelithiasis) or inflammation of the gallbladder (cholecystitis), initial medical interventions may include the use of medications to manage symptoms such as pain and nausea, as well as antibiotics to address any infections. In many cases, however, these medical measures are insufficient to resolve the underlying issue, particularly when gallstones or biliary obstruction occur.

77. In cases where gallstones cause significant obstruction of the bile ducts, surgical intervention can be necessary.

5. Deep Vein Thrombosis ("DVT") and PE

Risk of Gallbladder and Biliary Diseases: A Systematic Review and Meta-analysis of Randomized Clinical Trials, 182 JAMA Internal Med. 513 (2022) at 514-519.

[65] *Id.*; *see also,* Nauck *et al*., *Effects of Liraglutide Compared with Placebo on Events of Acute Gallbladder or Biliary Disease in Patients with Type 2 Diabetes at High Risk for Cardiovascular Events in the LEADER Randomized Trial*, 42 Diabetes Care 1912 (2019) at 1912 (showing, "Cholecystectomy was performed more frequently in liraglutide-treated patients (HR 1.56; 95% CI 1.10, 2.20; P = 0.013")).

78. DVT occurs when a blood clot forms in one of the body's deep veins, typically in the legs.[66] Treatment for DVT includes anticoagulant medications, and, in some instances, surgery.

79. DVT poses a serious risk to health because blood clots can break loose, travel through the bloodstream, and lodge in the lungs, causing a PE ("PE").[67] According to CDC, "sudden death is the first symptom in about one-quarter (25%) of people who have a PE."[68] The CDC estimates that 60,000 to 100,000 Americans die of DVT and PE every year.[69]

6. Micronutrient Deficiencies

80. Micronutrient deficiencies occur as a result of undernutrition and include but are not limited to deficiencies of vitamin C, D, thiamine or B12; and hypovitaminosis.

81. Gastroparesis—which, as discussed above, can be caused by GLP-1 RAs—can lead to micronutrient deficiencies due to the persistent symptoms associated with said delay in gastric motility (as discussed above), such as decreased appetite—leading to a significant caloric deficit—

[66] Though cases involving DVT—and venous thromboembolism ("VTE") generally—are not yet included as part of the MDL, there is currently an unopposed motion before the JPML to transfer DVT and VTE cases to the Eastern District of Pennsylvania to be included in this MDL. *See In re Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) Prods. Liability Litig.*, MDL No. 3094, JPML Docket No. 257 (Aug. 21, 2024).

[67] Mayo Clinic Staff, *Deep Vein Thrombosis (DVT)*, MAYO CLINIC (Jun. 11, 2022) https://www.mayoclinic.org/diseases-conditions/deep-vein-thrombosis/symptoms-causes/syc-20352557.

[68] *Data and Statistics on Venous Thromboembolism*, https://www.cdc.gov/blood-clots/data-research/facts-stats/index.html#:~:text=Sudden%20death%20is%20the%20first,die%20of%20VTE%20each%20year. (May 15, 2024), CDC.

[69] *Id.*

nausea, and vomiting.[70] "Common reported deficiencies include minerals such as iron, fat-soluble vitamins, thiamine and folate."[71]

82. Even more, prolonged gastric emptying is "proportional to the severity of nutritional deficiencies."[72]

83. Significant deficiencies in vital nutrients, such as Vitamins A, B, and D, magnesium, and potassium, among others, can lead to other serious conditions, such as osteopenia (bone disease), muscle wasting, anemia, vision impairment, deep vein thrombosis, PE, and a host of other conditions.[73]

84. It is recommended that dietary counseling and guidance be provided to patients taking medications, such as GLP-1 RAs, that are known to cause gastroparesis.[74] However, there are currently no "nutritional guidelines . . . for patients taking Ozempic or other [similar] medications . . . ."[75]

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[70] *See* Bharadwaj, *et al.*, *Management of gastroparesis-associated malnutrition*, J. DIGESTIVE DISEASES (2016) 17:285-294 ("Patients with GP are at a risk of significant nutritional abnormalities because of the debilitating symptoms. . . .").

[71] *Id.*

[72] *Id.* at 287 (citing Ogorek, *et al.*, *Idiopathic gastroparesis is associated with a multiplicity of severe dietary deficiencies*, AM. J. GASTROENTEROL. (1991) 86:423–8).

[73] *See, e.g.*, MALNUTRITION, JOHNS HOPKINS MEDICINE, located at https://www.hopkinsmedicine.org/health/conditions-and-diseases/malnutrition (last visited October 30, 2024); Jay Patel et al., *The Effects of Malnutrition on Inpatient Outcomes in Patients With Gastroparesis: A Nationwide Analysis*, CUREUS (2023) 15(10):e47082.

[74] *See* Ogorek, *et al.*, *Idiopathic gastroparesis is associated with a multiplicity of severe dietary deficiencies*, AM. J. GASTROENTEROL. (1991) 86:423–8; Parkman, *et al.*, *Dietary Intake and Nutritional Deficiencies in Patients With Diabetic or Idiopathic Gastroparesis*, GASTROENTEROL. (2011) 141:486-98 ("Nutritional consultation is obtained infrequently but is suggested for dietary therapy and to address nutritional deficiencies [in patients with gastroparesis].").

[75] Dani Blum, *An Extreme Risk of Taking Ozempic: Malnutrition*, N.Y. TIMES (Apr. 21, 2023), located at https://www.nytimes.com/2023/04/21/well/eat/ozempic-side-effects-malnutrition.html (last visited October 30, 2024). *See also* Sandra Christensen et al., *Dietary intake by patients taking*

85. To date, Defendants have failed to identify this need for prescribing much less educate them about it.

7. Wernicke's Encephalopathy

86. Related to a micronutrient deficiency, thiamine (vitamin B1) is an essential nutrient responsible for "mitochondrial energetics," including the production of adenosine triphosphate ("ATP").[76]

87. Gastroparesis-associated micronutrient deficiency can lead to a thiamine deficiency.[77]

88. Early symptoms of a thiamine deficiency include fatigue, irritability, mood lability, memory impairment, loss of appetite, and sleep disturbances, among others.[78]

89. More severe effects of thiamine deficiency include the development of Wernicke-Korsakoff Syndrome (including Wernicke's Encephalopathy and Korsakoff amnesic syndrome—which are "different stages of the same disease").[79]

90. Wernicke's Encephalopathy, which can be caused by dietary deficiencies and/or

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GLP-1 and dual GIP/GLP-1 receptor agonists: A narrative review and discussion of research needs, OBESITY PILLARS 11 (2024) 100121.

[76] Chandler Marrs & Derrick Lonsdale, *Hiding in Plain Sight: Modern Thiamine Deficiency*, CELLS (2021) 10:2595.

[77] Ryan F. Flanagan & Jennifer X. Cai, *Untangling the Link Between Gastroparesis, Micronutrient Deficiency, and Hair Loss*, DIG. DISEASES & SCIS. (2023) 68:1086-88 ("Though the literature has reported an association between gastroparesis symptoms and decreased intake of vitamin B12, vitamin C, folate, thiamine, niacin, magnesium, phosphorus, and zinc, testing for micronutrient deficiencies has not been routine clinical practice for these patients.") (internal citations omitted).

[78] Chandler Marrs & Derrick Lonsdale, *Hiding in Plain Sight: Modern Thiamine Deficiency*, CELLS (2021) 10:2595.

[79] WERNICKE-KORSAKOFF SYNDROME, NAT'L INST. OF NEUROLOGICAL DISORDERS AND STROKE, located at https://www.ninds.nih.gov/health-information/disorders/wernicke-korsakoff-syndrome (last visited October 30, 2024).

prolonged vomiting, is a life-threatening "degenerative brain disorder caused by the lack of vitamin B1" and is characterized by mental confusion, vision problems, coma, hypothermia, low blood pressure, and ataxia (or lack of muscle coordination).[80]

91. Treatment for Wernicke's Encephalopathy "involves replacement of thiamine and providing proper nutrition and hydration. In individuals with Wernicke's encephalopathy, it is "very important to start thiamine replacement before beginning nutritional replenishment." "Most symptoms of Wernicke's Encephalopathy can be reversed if detected and treated promptly and completely. However, improvement in memory function is slow and, usually, incomplete. Without treatment, these disorders can be disabling and life-threatening."[81]

8. Aspiration of Gastric Contents

92. Because GLP-1 RAs significantly delay gastric emptying, patients taking GLP-1 RAs "may be at an increased risk for gastric aspiration despite following proper fasting guidelines."[82]

93. Reports of pulmonary aspiration of gastric contents in patients taking GLP-1s has prompted significant attention to revising the guidelines around preoperative care.[83]

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[80] *Id.*

[81] *Id.*

[82] Nunez and Leavitt, *Glucagon-Like Peptide 1 Receptor Agonists and Aspiration Risk*, OPEN ANESTHESIA (08/23/2023), located at https://www.openanesthesia.org/keywords/glucagon-like-peptide-1-receptor-agonists-and-aspiration-risk/#:~:text=Because%20these%20medications%20significantly%20delay%20gastric%20emptying%2C%20surgical,to%20withhold%20these%20medications%20prior%20to%20elective%20surgery; *see also* van Zuylen, *et al*., *Perioperative management of long-acting glucagon-like peptide-1 (GLP-1) receptor agonists: concerns for delayed gastric emptying and pulmonary aspiration*, BRITISH J. ANAESTHESIA (2024) 132(4):644-48.

[83] *See* Tammy L. Kindel et al., *Multisociety Clinical Practice Guidance for the Safe Use of Glucagon-like Peptide-1 Receptor Agonists in the Perioperative Period*, CLINICAL GASTROENTEROL. & HEPATOL. (2024) (open access article), available at https://www.cghjournal.org/action/showPdf?pii=S1542-3565%2824%2900910-8.

94. Due to the "concerns of GLP-1 agonists-induced delayed gastric emptying and associated high risk of regurgitation and aspiration of gastric contents", the American Society of Anesthesiologists issued new guidelines, including:[84]

a. Holding GLP-1s on the day of surgery or, if on a weekly dose, holding the dose a week prior to the procedure.[85]

b. If gastrointestinal (GI) symptoms such as severe nausea/vomiting/retching, abdominal bloating, or abdominal pain are present, consider delaying elective procedure, and discuss the concerns of potential risk of regurgitation and pulmonary aspiration of gastric contents with the proceduralist/surgeon and the patient.[86]

c. If the patient has no GI symptoms, but the GLP-1 agonists were not held as advised, proceed with "full stomach" precautions or consider evaluating gastric volume by ultrasound, if possible and if proficient with the technique. If the stomach is empty, proceed as usual. If the stomach is full or if gastric ultrasound inconclusive or not possible, consider delaying the procedure or treat the patient as 'full stomach' and manage accordingly. Discuss the concerns of potential risk of regurgitation and pulmonary aspiration of gastric contents with the proceduralist/surgeon and the patient.[87]

95. In fact, due to these concerns the FDA required all Defendants to update the labels of their GLP-1 RAs with a warning regarding pulmonary spiration during general anesthesia or deep sedation.[88] The new label reads "[GLP-1 RA drug] delays gastric emptying . . . There have been rare postmarketing reports of pulmonary aspiration in patients receiving GLP-1 receptor agonists undergoing elective surgeries or procedures requiring general anesthesia or deep sedation who had residual gastric contents despite reported adherence to preoperative fasting

[84] https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/american-society-of-anesthesiologists-consensus-based-guidance-on-preoperative

[85] *Id.*

[86] *Id.*

[87] *Id.*

[88] This additional warning was not implemented until Nov. 6, 2024, leaving many patients without any warning of these risks. *See* https://www.webmd.com/obesity/news/20241106/new-fda-warning-added-popular-weight-loss-drugs

recommendations."[89]

C. GLP-1 RAs ARE INEFFECTIVE IN MANY PATIENTS BECAUSE OF HIGH DISCONTINUATION RATES, MINIMAL TO NO WEIGHT LOSS FOR A SIGNIFICANT PERCENTAGE OF PATIENTS AND SUBSEQUENT REBOUND WEIGHT GAIN

96. Many patients find GLP-1 RAs ineffective because they discontinue use of the drugs.

97. In May 2024, Blue Cross Blue Shield published an "Issue brief" that examined whether "patients prescribed [GLP-1 RAs] for weight loss are dropping out of treatment too quickly to attain the health benefits of these drugs." The company reviewed the behavior of nearly 170,000 GLP-1 RA users covered by Blue Cross Blue Shield and concluded that 30% of GLP-1 RA patients discontinued treatment within 4 weeks, that 58% of GLP-1 RA patients discontinued treatment within 180 days, and that patients who discontinue shortly after starting GLP-1 RA therapy are unlikely to see *any* health benefits.[90] As a result, Blue Cross Blue Shield of Michigan, the largest health insurer in the state, announced a plan to greatly restrict coverage for GLP-1 RA prescriptions, citing concerns about efficacy and safety.[91]

98. In June 2024, a real-world study of 4,066 insured GLP-1 RA weight-loss patients concluded that only 1 in 3 patients remained on GLP-1 RAs at one year, which "is substantially lower than what has been reported in clinical trials." The authors also concluded that the high

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[89] *Id.*

[90] *Real-world trends in glp-1 treatment persistence and prescribing for weight management*, Blue Health Intelligence Issue Brief (2024) (https://www.bcbs.com/media/pdf/BHI_Issue_Brief_GLP1_Trends.pdf).

[91] Blue Cross Blue Shield of Michigan, *Changes coming for select weight loss drugs for some commercial members* (July 2024), *available at* https://www.bcbsm.com/content/dam/microsites/corpcomm/provider/the_record/2024/jul/Record_0724h.html (last visited 10/8/24).

discontinuation rates for GLP-1 RAs "create GLP-1 obesity treatment effectiveness concerns" because the value of the treatment "is not likely to be realized if [the GLP-1 RA] is discontinued during the first year and weight loss is not achieved or maintained."[92]

99. Published in March 2021, a study funded by Novo acknowledged that weight loss for semaglutide users is likely to plateau between weeks 60 and 68 and that patients who discontinued use of semaglutide "gradually regained weight."[93]

100. Another study funded by Novo, which was published in February 2022, concluded that withdrawal of once-weekly semaglutide "led to most of the weight loss being regained within 1 year."[94]

101. A systematic review and network meta-analysis published in January 2024 reported that the effects of GLP-1 RAs on body weight gradually decline during long term use, indicating "potential limitations of GLP-1 RAs for sustained long term weight loss efforts."[95]

102. There are also some percentage of people who do not respond to GLP-1 RAs for weight-loss at all (research suggests that approximately 14% of patients taking lost less than 5%

[92] Patrick P. Gleason, *Real-world persistence and adherence to glucagon-like peptide-1 receptor agonists among obese commercially insured adults without diabetes*, J. Managed Care + Specialty Pharm. (June 2024) (https://www.jmcp.org/doi/10.18553/jmcp.2024.23332).

[93] Rubino, *et al*., *Effect of Continued Weekly Subcutaneous Semaglutide vs Placebo on Weight Loss Maintenance in Adults with Overweight or Obesity: The STEP 4 Randomized Clinical Trial*, JAMA (March 2021) available at https://jamanetwork.com/journals/jama/fullarticle/10.1001/jama.2021.3224).

[94] Wilding, *et al*., *Weight regain and cardiometabolic effects after withdrawal of semaglutide: The STEP 1 trial extension*, Diabetes Obes. Metab. (Feb. 2022) (https://dom-pubs.onlinelibrary.wiley.com/doi/10.1111/dom.14725).

[95] Yao, *et al*., *Comparative effectiveness of GLP-1 receptor agonists on glycaemic control, body weight, and lipid profile for type 2 diabetes: systematic review and network meta-analysis*, BMJ (Jan. 2024) (http://dx.doi.org/10.1136/bmj-2023-076410).

of their body weight and one-third lost less than 10% of their body weight).[96]

103. In contrast to GLP-1 RAs, studies show that bariatric surgery is highly effective to treat type 2 diabetes and obesity, and to improve mortality for such patients.[97] Not only is bariatric surgery far more effective, it is also safer[98] and more cost-effective[99] than GLP-1 RAs.

104. Likewise, other, well-established, prescription and over-the-counter medications with FDA approval for weight loss are available and offer significantly lower risk profiles than GLP-1 RAs. For example, Orlistat, an over-the-counter medication, was FDA-approved for weight loss in 1999 and has been shown to reduce fat absorption by up to 30%. While associated with some gastrointestinal adverse effects, they are much less severe than those seen with GLP-1 RAs

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[96] Carbajal, Erica, *Up to 15% of patients on weight loss drugs may be 'non-responders*, Becker's Hospital Review (April 1, 2024) available at https://www.beckershospitalreview.com/glp-1s/up-to-15-of-patients-on-weight-loss-drugs-non-responders.html.

[97] *See, e.g.*, Courcoulas, *et al*., *Long-term outcomes of medical management vs bariatric surgery in type 2 diabetes*, 331 JAMA 654 (2024) ("After 7 to 12 years of follow-up, individuals originally randomized to undergo bariatric surgery compared with medical/lifestyle intervention had superior glycemic control with less diabetes medication use and higher rates of diabetes remission."), available at https://pubmed.ncbi.nlm.nih.gov/38411644/ (last visited 10/21/24); Syn, *et al*., *Association of metabolic-bariatric surgery with long-term survival in adults with and without diabetes: a one-stage meta-analysis of matched cohort and prospective controlled studies with 174772 participants*, 397 Lancet 1830 (2021) ("Median life expectancy was approximately 9.3 years (95% CI 7.1–11.8) longer for patients with diabetes in the surgery group than in the control group. […] Among adults with obesity, metabolic–bariatric surgery is associated with substantially lower all-cause mortality rates and longer life expectancy than usual obesity management."), available at https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00591-2/abstract (last visited 10/21/24).

[98] *See, e.g.*, Dicker, *et al*., *Bariatric metabolic surgery vs glucagon-like peptide-1 receptor agonists and mortality*, JAMA Open (2024) (finding bariatric metabolic surgery to be "associated with a 62% reduction in mortality compared with GLP-1 RAs"), available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2819703 (last visited 10/21/24).

[99] *See, e.g.*, Tina Reed, *Bariatric surgery found more cost-effective than GLP-1s*, Axios, available at https://www.axios.com/2024/10/21/bariatric-surgery-more-cost-effective-glp1 (last visited 10/21/24); Sanchez, *et al*., *Comparative Cost-Effectiveness Analysis of Bariatric Surgery and GLP-1 Receptor Agonists for the Management of Obesity*, Northwestern University Feinberg School of Medicine, available at https://www.surgery.northwestern.edu/docs/edelstone-bendix-research-poster/2024-posters/Sanchez-Joseph.pdf (last visited 10/21/24).

and include fatty stools, fecal urgency, incontinence, and increased defecation.[100] Similarly, a prescription appetite suppressant combining phentermine and topiramate has been approved since 2012 and has been shown effective for long-term weight loss. While contraindicated in pregnancy, other risks are generally non-severe and include dizziness, constipation, dry mouth, and inattention.[101]

105. Similarly, an alternate treatment of type 2 diabetes is Metformin. Johns Hopkins' "Patient Guide to Diabetes" describes Metformin as the "treatment of choice for type 2 diabetes." This guide describes Metformin as "very effective at controlling blood glucose and lowers A1C as much as 15%." The listed side effects include diarrhea and rare lactic acidosis.[102] Meanwhile, "in studies of GLP-1 receptor agonists used alone or in combination with oral antihyperglycemic therapies, mean changes in A1C ranged from −0.8 to −1.7%"[103]

106. A meta-analysis of Metformin found "there is no significant risk of GI AEs associated neither with the dose size of metformin nor metformin treatment duration." This same study found "GLP-1 RA and acarbose were ranked as having the highest incidence of GI AEs."[104]

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[100] Filippatos, *et al*., *Orlistat-associated adverse effects and drug interactions: a critical review.* Drug Saf. 2008;31(1):53-65.

[101] Lei XG, *et al*., *Efficacy and Safety of Phentermine/Topiramate in Adults with Overweight or Obesity: A Systematic Review and Meta-Analysis.* Obesity (Silver Spring). 2021 June;29(6):985-994.

[102] https://hopkinsdiabetesinfo.org/medications-for-type-2-diabetes-metformin/#:~:text=Metformin%20is%20very%20effective%20at,preparations%20can%20often%20prevent%20this (last accessed November 10, 2024).

[103] https://diabetesjournals.org/spectrum/article/30/3/202/32399/Glucagon-Like-Peptide-1-Receptor-Agonists-for-Type

[104] Nabrdalik, *et al*., *Gastrointestinal adverse events of metformin treatment in patients with type 2 diabetes mellitus: A systematic review, meta-analysis and meta-regression of randomized controlled trials*, Front Endocrinol (Lausanne) (Sept. 14 2022) 13:975912. doi: 10.3389/fendo.2022.975912. PMID: 36187122; PMCID: PMC9524196.

Therefore, GLP-1 RAs offer minimal increased benefit as it relates to diabetes while increasing the frequence of gastrointestinal adverse injuries.

D. THE REGULATORY HISTORY OF NOVO NORDISK'S GLP-1 RAs

1. Ozempic

107. On October 19, 2008, Novo filed an Investigational New Drug ("IND") application for Ozempic (semaglutide).[105]

108. On December 5, 2016, Novo announced submission of a New Drug Application ("NDA") 209637 to the FDA for regulatory approval of once-weekly injectable semaglutide, a new glucagon-like peptide-1 (GLP-1) medication for treatment of type 2 diabetes. In the announcement, Novo represented that in clinical trials "once-weekly semaglutide had a safe and well tolerated profile with the most common adverse event being nausea."[106]

109. On December 5, 2016, Novo submitted NDA 209637, requesting that the FDA grant it approval to market and sell Ozempic (semaglutide) 0.5 mg or 1 mg injection in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. On December 5, 2017, the FDA approved NDA 209637.[107]

110. On March 20, 2019, Novo submitted supplemental new drug application (sNDA) 209637/S-003 for Ozempic (semaglutide) 0.5 mg or 1 mg injection, requesting approval to expand its marketing of Ozempic by adding an indication to reduce the risk of major adverse

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[105] Determination of Regulatory Period for Ozempic (11/29/19) available at https://www.federalregister.gov/documents/2019/11/29/2019-25850/determination-of-regulatory-review-period-for-purposes-of-patent-extension-ozempic.

[106] Novo Nordisk, *Novo Nordisk files for regulatory approval of once-weekly semaglutide in the US and EU for the treatment of type 2 diabetes* (Dec. 5, 2016), available at https://ml.globenewswire.com/Resource/Download/d2f719e1-d69f-4918-ae7e-48fc6b731183.

[107] FDA Approval Letter for NDA 209637 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209637s000ltr.pdf.

cardiovascular events in adults with type 2 diabetes and established cardiovascular disease.[108] On January 16, 2020, the FDA approved sNDA 209637/S-003 for cardiovascular risk reduction in adults with Type 2 diabetes and known heart disease.[109]

111. On May 28, 2021, Novo submitted sNDA 209637/S-009, requesting approval for a higher 2 mg dose of Ozempic (semaglutide) injection. On March 28, 2022, the FDA approved sNDA 209637/S-009 for a higher-dose Ozempic 2 mg injection for increased glycemic control in adults with type 2 diabetes.[110]

112. On September 22, 2023, Novo added "ileus" under Section 6-3 Postmarketing Experience of the Prescribing Information ("PI" or "label") in a revised Ozempic label. The new label listed ileus as an adverse reaction reported during post-approval use of semaglutide, the active ingredient of Ozempic.[111]

2. Wegovy

113. On December 4, 2020, Novo announced submission of NDA 215256 to the FDA for regulatory approval of subcutaneous semaglutide 2.4 mg, a once-weekly glucagon-like peptide-1 (GLP-1) medication for chronic weight management. In the announcement, Novo represented that "once-weekly semaglutide 2.4 appeared to have a safe and well-tolerated profile" and "[t]he

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[108] *Novo Nordisk files for US FDA approval of oral semaglutide for blood sugar control and cardiovascular risk reduction in adults with type 2 diabetes*, Cision PR Newswire (March 20, 2019), available at https://www.prnewswire.com/news-releases/novo-nordisk-files-for-us-fda-approval-of-oral-semaglutide-for-blood-sugar-control-and-cardiovascular-risk-reduction-in-adults-with-type-2-diabetes-300815668.html.

[109] FDA Supplement Approval Letter for NDA 209637/A-003 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209637Orig1s003ltr.pdf.

[110] FDA Supplement Approval Letter for NDA 209637/S-009 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/209637Orig1s009ltr.pdf.

[111] Ozempic Label (dated 9/22/23), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf.

most common side effects were gastrointestinal and were transient, and mild or moderate in severity."[112]

114. On December 4, 2020, Novo submitted NDA 215256, requesting that the FDA grant it approval to market and sell Wegovy (semaglutide) injection in the United States as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial BMI of either 30/kg/m^2 or greater (obese), or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition. On June 4, 2021, the FDA approved NDA 215256.[113]

115. On June 29, 2022, Novo submitted supplemental new drug application (sNDA) 215256/S-005 for Wegovy (semaglutide) injection, requesting approval for the addition of an indication for use in adolescents 12 years and older with an initial BMI at or above the 95th percentile for age and sex. On December 23, 2022, the FDA approved sNDA 215256/S-005.[114]

116. On December 23, 2022, Novo announced the FDA's approval of sNDA 215256/S-005 for a new indication of Wegovy to treat obesity in teens aged 12 years and older. In the press release, Novo touted the "safety and efficacy of Wegovy as a treatment for adolescents with obesity[.]"[115] As with its prior press releases, Novo disclosed Important Safety Information and

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[112] Novo Nordisk, *Novo Nordisk files for regulatory approval of once-weekly semaglutide 2.4 mg for weight management*, (Dec. 4, 2020), available at https://www.globenewswire.com/news-release/2020/12/04/2139776/0/en/Novo-Nordisk-files-for-US-FDA-regulatory-approval-of-once-weekly-semaglutide-2-4-mg-for-weight-management.html.

[113] FDA Approval Letter for NDA 215256 (Wegovy), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/215256Orig1s000ltr.pdf.

[114] FDA Supplement Approval Letter for NDA 215256/S-005(Wegovy), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/215256Orig1s005ltr.pdf.

[115] Novo Nordisk, *FDA approves once-weekly Wegovy injection for the treatment of obesity in teens aged 12 years and older* (Dec. 23, 2022), available at https://www.novonordisk-us.com/media/news-archive/news-details.html?id=151389.

provided links to the Medication Guide and Prescribing Information, but gastroparesis was not warned of as a side effect or risk.

117. On September 23, 2022, Novo submitted sNDA 215256/S-007, requesting approval for an update to the Prescribing Information and Medication Guide to include Wegovy (semaglutide) 1.7 mg subcutaneous weekly as an additional maintenance dose. On July 21, 2023, the FDA approved sNDA 215256/S-007.[116]

118. In December 2022, Novo added "ileus" to its Postmarketing Section in a revised Wegovy label.[117] The new label listed ileus as an adverse reaction reported during post-approval use of semaglutide, the active ingredient of Wegovy.

3. Rybelsus

119. On March 20, 2019, Novo announced the submission of NDA 213051 to the FDA for regulatory approval for oral semaglutide, under the brand name Rybelsus, the first once-daily glucagon-like peptide-1 receptor agonist for blood sugar control and cardiovascular risk reduction in adults with type 2 diabetes.[118]

120. On March 20, 2019, Novo submitted NDA 213051, requesting that the FDA grant it approval to market and sell Rybelsus (oral semaglutide) in both 7 mg and 14 mg oral doses in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type

[116] FDA Supplement Approval Letter for NDA 215256/S-007(Wegovy), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/215256Orig1s007ltr.pdf.

[117] Wegovy Label (dated December 23, 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215256s005lbl.pdf.

[118] *Novo Nordisk files for US FDA approval of oral semaglutide for blood sugar control and cardiovascular risk reduction in adults with type 2 diabetes,* Cision PR Newswire (Mar. 20, 2019), available at https://www.prnewswire.com/news-releases/novo-nordisk-files-for-us-fda-approval-of-oral-semaglutide-for-blood-sugar-control-and-cardiovascular-risk-reduction-in-adults-with-type-2-diabetes-300815668.html.

2 diabetes mellitus.[119] On September 20, 2019, the FDA approved NDA 213051.[120]

121. On December 10, 2019, Novo submitted a supplemental new drug application (NDA 213051/S-001) for Rybelsus (semaglutide) asking "for the addition of efficacy and safety information to the prescribing information based on clinical data from the PIONEER 6 cardiovascular outcomes trial entitled, 'A trial investigating the cardiovascular safety of oral semaglutide in subjects with type 2 diabetes.'"[121] On January 16, 2020, the FDA approved NDA 213051/S-001.[122]

122. On March 28, 2022, the FDA notified Novo of new safety information that it determined should be included in the labeling for GLP-1 RAs pertaining to the risk of acute gallbladder disease. On April 27, 2022, Novo submitted a supplemental new drug application (NDA 213051/S-011) and amendments for Rybelsus (semaglutide) tablets incorporating the FDA's required safety modifications to the label. On June 10, 2022, the FDA provided supplemental approval for NDA 213051/S-011.[123]

123. On July 15, 2022, Novo submitted a supplemental new drug application (NDA 123051/S-012) for Rybelsus to remove the "Limitation of Use" statement "Not recommended as

[119] Clinical Review for NDA 213051 (Rybelsus), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/213051Orig1s000MedR.pdf (last visited 9/22/23).

[120] FDA Approval Letter for NDA 213051 (Rybelsus), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/213051Orig1s000ltr.pdf.

[121] FDA Approval Letter available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213182Orig1s000Approv.pdf.

[122] FDA Approval Letter for NDA 213051/S-001 (Rybelsus), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/213182Orig1s000,%20213051Orig1s001ltr.pdf.

[123] FDA Approval Letter for NDA 123051/S-011 (Rybelsus) available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/213051Orig1s011ltr.pdf.

first-line therapy for patients inadequately controlled on diet and exercise" in the "Prescribing Information and Medication Guide" ("PI"). The following updates were also made to the PI information: a) addition of Pancreatitis and Diabetic Retinopathy Complications to the Other Adverse Reactions subsection in section 6.1, Clinical Trials Experience; b) updating the Immunogenicity section and moving it from section 6.2 to section 12.6; c) adding "Gastrointestinal: ileus" to section 6.2, Postmarketing Experience; d) revising section 7.1, Concomitant Use with an Insulin Secretagogue (*e.g.*, Sulfonylurea) or with insulin; and e) other minor grammatical changes. The FDA approved NDA 123051/S-012 on January 12, 2023.[124]

124. On January 12, 2023, Novo announced the FDA's approval of NDA 123051/S-012 for the label update described above. In the press release, Novo emphasized that "Rybelsus has been prescribed to hundreds of thousands of patients to help improve glycemic control[,]" and they disclosed Important Safety Information about Rybelsus and provided links to its Medication Guide and Prescribing Information, gastroparesis was not warned of as a side effect or risk.[125]

4. Victoza

125. On March 23, 2008, Novo submitted NDA 022341, requesting that the FDA grant it approval to market and sell Victoza (liraglutide [rDNA origin]) injection, solution for subcutaneous use, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

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[124] *Novo Nordisk announces FDA approval of label update for Rybelsus® (semaglutide) allowing use as a first-line option for adults with type 2 diabetes*, Cision PR Newswire (Jan. 12, 2023), available at https://www.prnewswire.com/news-releases/novo-nordisk-announces-fda-approval-of-label-update-for-rybelsus-semaglutide-allowing-use-as-a-first-line-option-for-adults-with-type-2-diabetes-301720965.html.

[125] Novo Nordisk, *Novo Nordisk announces FDA approval of label update for Rybelsus® (semaglutide) allowing use as a first-line option for adults with type 2 diabetes* (Jan. 12, 2023), available at https://www.novonordisk-us.com/media/news-archive/news-details.html?id=154651.

126. Also on May 23, 2008, Novo applied for marketing authorization to the European Medicines Agency in Europe.[126] On July 3, 2009, Novo issued a press release that the European Commission granted it marketing authorization for Victoza for the treatment of type 2 diabetes. The authorization covered all 27 European Union member states.[127]

127. On January 25, 2010, the FDA approved (NDA 022341) Victoza (liraglutide) injection to improve glycemic control in adults with type 2 diabetes.[128] On the same day, the FDA issued a Q&A regarding the safety requirements for Victoza.[129] The FDA noted that "Victoza … is not recommended as a first-line therapy for patients whose blood sugar is not controlled through diet and exercise." The FDA listed safety concerns that healthcare professionals should be aware of, including pancreatitis and medullary thyroid cancer; however, noted that "the Agency believes that the benefits of this drug to patients with T2DM outweigh potential risks associated with its use."

128. In 2010, Novo breached the Association of the British Pharmaceutical Industry's ("ABPI") code of conduct by failing to provide information about side effects of liraglutide, the active ingredient in both Victoza and Saxenda, prior to it being granted market authorization.[130]

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[126] Novo Nordisk Press Release (dated 7/3/09), available at https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=3441.

[127] Novo Nordisk Press Release (dated 7/3/09), available at https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=3441.

[128] FDA Approval Letter for NDA 22341 (Victoza), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022341s000approv.pdf.

[129] FDA Questions and Answers – Safety Requirements for Victoza (March 23, 2008), available at https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-safety-requirements-victoza-liraglutide.

[130] PMCPA, *Novo Nordisk Limited, Eli Lilly and Company Limited, Grunenthal Ltd and Napp Pharmaceuticals Limited named in advertisements for breaches of the ABPI Code of Practice*

129. On April 19, 2012, consumer advocacy group, Public Citizen, petitioned the FDA to immediately remove Victoza (liraglutide) from market because they concluded that the risks of thyroid cancer and pancreatitis outweighed any documented benefits.[131]

130. On September 5, 2017, Novo agreed to pay $58.65 Million to settle multiple whistleblower lawsuits that the company had illegally marketed, promoted, and sold Victoza for off-label uses in violation of the FDCA and False Claims Act.[132] Novo paid an additional $1.45 Million to California and Illinois to settle whistleblower cases alleging fraud against private commercial health insurers.[133]

131. On June 17, 2019, the FDA approved Victoza (liraglutide) injection for the treatment of pediatric patients 10 years of age or older with type 2 diabetes.[134] The FDA granted this application on priority review. Novo issued a press release the same day indicating that Victoza (liraglutide) injection 1.2 or 1.8 mg is an injectable prescription medication used along with diet and exercise to lower blood sugar in adults and children over 10 years of age with type 2 diabetes, and to reduce the risk of major cardiovascular events such as heart attack, stroke, or death in adults

(Dec. 14, 2010), https://www.pmcpa.org.uk/about-us/media/news/novo-nordisk-limited-eli-lilly-and-company-limited-grunenthal-ltd-and-napp-pharmaceuticals-limited-named-in-advertisements-for-breaches-of-the-abpi-code-of-practice/.

[131] Public Citizen Statement (April 19, 2012), available at https://www.citizen.org/news/statement-of-jonah-minkoff-zern-senior-organizer-public-citizens-democracy-is-for-people-campaign/.

[132] Department of Justice Press Release (Sept. 5, 2017), available at https://www.justice.gov/opa/pr/novo-nordisk-agrees-pay-58-million-failure-comply-fda-mandated-risk-program.

[133] Phillips & Cohen Statement (Sept. 5, 2017), available at https://www.phillipsandcohen.com/novo-nordisk-whistleblower-settlement-victoza/.

[134] FDA News Release (June 7, 2019), available at https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-pediatric-patients-type-2-diabetes.

with type 2 diabetes with known heart disease.[135]

132. On July 5, 2023, a supplemental approval added 'ileus' as a gastrointestinal adverse reaction reported during post-approval use of Victoza in the prescribing information (PI) to Section 6.2 Postmarketing Experience.[136]

5. Saxenda

133. On December 20, 2013, Novo submitted NDA 206321, requesting that the FDA grant it approval to market and sell Saxenda (liraglutide 3 mg) in the United States as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial BMI of either 30/kg/m^2 or greater (obese), or 27 kg/m^2 or greater (overweight) combined with at least one weight-related comorbid condition.

134. Following receipt of NDA 206321, and prior to Saxenda's approval, Novo submitted 60 amendments to its original application dated in 2014: January 10; February 6, 13, and 14; March 4 and 21; April 2 (3), 11, 15, 18, and 29; May 1, 2 (2), 23, and 27; June 6, 16, 18, and 26; July 1, 3, 8, 9, 11, 14, and 15 (2); August 14 (2), 20, 28, and 29; September 24, 26, and 29 (2); October 1 (2), 2, 3 (2), 6, 7, 9, 15, 17 (2), 18, 20 and 24; November 10 (2) and 18; and December 12,16, 17, and 18.[137]

135. Following the receipt of several amendments, the FDA approved NDA 206321 on December 23, 2014.[138]

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[135] Novo Nordisk Press Release (June 17, 2019), available at https://www.novonordisk-us.com/media/news-archive/news-details.html?id=36638.

[136] Victoza Label (July 5, 2023), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022341s039lbl.pdf.

[137] FDA Approval Letter for NDA 206321 (Saxenda), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/206321Orig1s000Approv.pdf.

[138] *Id.*

136. At the same time, Novo was seeking approval for Saxenda from health organizations worldwide. Health Canada approved Saxenda for chronic weight management in February 2015. The European Commission authorized Saxenda for marketing throughout the European Union (EU) to help manage weight in adults in March 2015.[139]

137. On April 26, 2017, the FDA approved an updated Saxenda injectable 3 mg label, based on the findings of the SCALE Obesity and Pre-diabetes 3-year trial.[140]

138. On December 4, 2020, the FDA approved Novo's supplemental NDA for Saxenda for chronic weight management in pediatric patients aged 12 years and older who are obese, as defined by specific BMI cut-offs for age and sex that correspond to BMI 30 kg/m^2 or higher for adults, and who weigh more than 60 kg (132 pounds).[141] In the press release, Novo touted the "safety and efficacy of Saxenda as a treatment for adolescents with obesity[.]"[142] As with its prior press releases, Novo disclosed Important Safety Information and provided links to the Medication Guide and Prescribing Information, but gastroparesis and its sequelae were not warned of as a side effect or risk.

139. On April 20, 2023, a supplemental approval added 'ileus' as a gastrointestinal adverse reaction reported during post-approval use of liraglutide in the prescribing information

[139] Clinical Trials Arena, *Saxenda (liraglutide) for the treatment of obesity, US* (Aug. 4, 2023), available at https://www.clinicaltrialsarena.com/projects/saxenda-liraglutide-obesity/?cf-view.

[140] FDA Supplemental Approval for NDA 206321/S-004, available at https://www.accessdata.fda.gov/drugsatfda docs/nda/2019/206321Orig1s004.pdf (last visited 11/20/23).

[141] FDA Supplemental Approval for NDA 206321/S-012, -013, -014, available at https://www.accessdata.fda.gov/drugsatfda docs/appletter/2020/206321Orig1s012,%20s013,%20s014ltr.pdf (last visited 11/20/23).

[142] Novo Nordisk, *FDA approves Saxenda for the treatment of obesity in adolescents aged 12-17* (Dec. 4, 2020), available at https://www.prnewswire.com/news-releases/fda-approves-saxenda-for-the-treatment-of-obesity-in-adolescents-aged-12-17-301186800.html.

(PI) to Section 6.2 Postmarketing Experience.[143]

E. THE REGULATORY HISTORY OF ELI LILLY'S GLP-1 RAs

1. Trulicity

140. On September 18, 2014, the FDA approved Lilly's Biologics License Application ("BLA") for dulaglutide "as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus" to be marketed as Trulicity in "single dose pre-filled syringes and pre-filled pens." As initially approved, the recommended dose for Trulicity was 1.5 mg per week.[144]

141. On April 19, 2019, Lilly submitted supplemental BLA 125469/S-033, requesting approval to expand its marketing of Trulicity by adding an indication for reduction of major cardiovascular events in adults with type 2 diabetes. On February 21, 2020, the FDA approved the request.[145]

142. On November 4, 2019, Lilly submitted BLA 125469/S-036, seeking approval for higher doses (3 mg per week and 4.5 mg per week) of Trulicity. On September 3, 2020, the FDA approved that request.[146]

143. On May 17, 2022, Lilly submitted BLA 125469/S-051, seeking to add an indication for a new patient population: "pediatric patients 10 years of age and older with type 2 diabetes

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[143] Saxenda Label (April 20, 2023), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/206321s016lbl.pdf.

[144] FDA Approval Letter for BLA 125469/0 (Sept. 18, 2014), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/125469Orig1s000ltr.pdf.

[145] FDA Approval Letter for BLA 125469/S-033 (Feb. 21, 2020), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/125469Orig1s033ltr.pdf.

[146] *See News Release: FDA approves additional doses of Trulicity (dulaglutide) for the treatment of type 2 diabetes,* Eli Lilly (Sept. 3, 2020) available at https://investor.lilly.com/news-releases/news-release-details/fda-approves-additional-doses-trulicityr-dulaglutide-treatment.

mellitus."

144. On November 17, 2022, the FDA approved the drug for pediatric use.[147] The supplemental approval also added 'ileus' as a gastrointestinal adverse reaction reported during post-approval use of Trulicity in the prescribing information (PI) to Section 6.2 Postmarketing Experience.[148]

2. Mounjaro

145. On September 14, 2021, Lilly submitted NDA 215866 Mounjaro (tirzepatide) injection as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. On May 13, 2022, the FDA approved NDA 215866.[149]

146. On May 13, 2022, Lilly announced the FDA's approval of NDA 215866 Mounjaro (tirzepatide) injection as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. In the press release, Lilly disclosed a safety summary and provided a link to the Medication Guide and Prescribing Information, but gastrointestinal injuries like gastroparesis and other delayed emptying conditions were not warned of as a risk.[150]

147. On July 28, 2023, a supplemental approval added 'ileus' as a gastrointestinal adverse reaction reported during post-approval use of Mounjaro in the Prescribing Information (PI) to Section 6.2 Postmarketing Experience.[151]

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[147] FDA Approval Letter for BLA 125469/S-051 (Nov. 17, 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/125469Orig1s051ltr.pdf.

[148] Trulicity Label (November 17, 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf.

[149] FDA Approval Letter for NDA 215866 (Mounjaro) available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/215866Orig1s000ltr.pdf.

[150] Mounjaro Label (May 13, 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215866s000lbl.pdf.

[151] Mounjaro Label (dated July 28, 2023), available at

3. Zepbound

148. Tirzepatide (the active ingredient in Zepbound) was first approved under the brand name Mounjaro in May 2022 to improve glycemic control in adults with type 2 diabetes.

149. Zepbound is a GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 agonist by activating the receptors for the natural incretin hormones GIP and GLP-1 to decrease food intake and slow gastric emptying.

150. On May 8, 2023, Lilly submitted NDA 217806 for Zepbound (tirzepatide) injection as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial BMI of either 30 kg/m2 or greater (obesity) or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (*e.g.*, hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease).[152]

151. On November 8, 2023, the FDA approved Zepbound for chronic weight management in adults with obesity (BMI of 30 kg/m2 or greater) or who are overweight (BMI of 27 kg/m2 or greater) with at least one weight-related condition for use, in addition to a reduced calorie diet and increased physical activity.[153]

152. In the FDA's November 8, 2023 news release, the FDA indicated that Zepbound can cause side effects including "nausea, diarrhea, vomiting, constipation, abdominal (stomach) discomfort and pain, injection site reactions, fatigue, hypersensitivity (allergic) reactions (typically

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https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215866Orig1s002s006lbl.pdf.

[152] FDA Approval Letter (dated November 8, 2023), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/217806Orig1s000ltr.pdf.

[153] *Id.*

fever and rash), burping, hair loss and gastroesophageal reflux disease."[154] Moreover, the FDA cautioned that Zepbound contains warnings for "inflammation of the pancreas (pancreatitis), gallbladder problems, hypoglycemia (blood sugar that is too low), acute kidney injury, diabetic retinopathy (damage to the eye's retina) in patients with type 2 diabetes mellitus and suicidal behavior or thinking." Zepbound's original label included "ileus" in Section 6.2 – Post-Marketing Experience as a gastrointestinal adverse reaction reported during post-approval use of tirzepatide.[155]

153. Lilly also issued a press release on November 8, 2023, regarding Zepbound's approval.[156] The press release listed the most commonly reported adverse events as being "nausea, diarrhea, vomiting, constipation, abdominal pain, dyspepsia, injection-site reactions, fatigue, hypersensitivity reactions, eructation, hair loss and gastroesophageal reflux disease." Lilly also noted that "most nausea, diarrhea and vomiting occurred when people increased their dose – but the effects generally decreased over time." Lilly indicated that Zepbound had a boxed warning regarding thyroid C-cell tumors, and that Zepbound is contraindicated in patients with a personal or family history of medullary thyroid carcinoma, in patients with multiple endocrine neoplasia syndrome type 2, and in patients with known serious hypersensitivity to tirzepatide or any of the excipients in Zepbound.

154. On November 20, 2023, Lilly submitted a supplemental NDA 217806/S-003 (sNDA) which provided for the addition of a single-dose vial container closure system for

[154] FDA Press Release (Nov. 8, 2023), available at https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management.

[155] Zepbound label (Nov. 8, 2023) available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217806s000lbl.pdf.

[156] Eli Lilly Press Release (Nov. 8, 2023), available at https://investor.lilly.com/news-releases/news-release-details/fda-approves-lillys-zepboundtm-tirzepatide-chronic-weight.

tirzepatide and for the expansion of quality control testing for the tirzepatide single-dose vial presentation. The sNDA did not include any changes with respect to the identification of ileus as a gastrointestinal adverse reaction in Section 6.2 of the label.[157] The FDA approved the sNDA on March 28, 2024.

F. DEFENDANTS WERE ON NOTICE THAT THERE IS REASONABLE EVIDENCE OF ASSOCIATION BETWEEN GLP-1 RAs AND GASTROPARESIS, ILEUS, INTESTINAL OBSTRUCTION, AND THEIR SEQUELAE

155. As previously discussed, GLP-1 RAs are treated as a class by the FDA, and the class of drugs shares a similar mechanism of action, similar physiologic effect, and similar chemical structure.

156. Although natural GLP-1—which is released when food is consumed—causes slowed motility, multiple studies have shown that GLP-1 RAs like liraglutide can delay gastric emptying for as long as least 16 weeks in some patients.[158] Further, for some GLP-1 RA patients, the effect on gastric emptying is greater and longer lasting. In one study of obese liraglutide users, researchers found that 57% developed "very significant" delay in gastric emptying as early as 5 weeks. For some liraglutide patients, the delay in gastric emptying lessened by 16 weeks of use, through tachyphylaxis (rapidly diminishing response to successive doses). However, for 30% of liraglutide patients, significant delay in gastric emptying persisted at 16 weeks. The authors of that study concluded that "[c]onsideration of this complication should be included in appraising the

[157] Zepbound Label (Mar. 28, 2024), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217806s003lbl.pdf.

[158] Halawi, *et al*., *Effects of liraglutide on weight, satiation, and gastric functions in obesity: a randomised, placebo-controlled pilot trial*, 2 Lancet 890 (2017); Maselli, *et al*., *Effects of liraglutide on gastrointestinal functions and weight in obesity: A randomized clinical and pharmacogenomic trial*, 30 Obesity Society 1608 (2022).

benefit to risk ratio of GLP-1 RA therapy."[159]

157. Persistent delayed gastric emptying has been recognized in GLP-1 RA literature for several years.[160]

158. By 2002, it was known that GLP-1 RAs cause prolonged cessation of intestinal motility in rats.[161]

159. By January 2016, it was recognized that GLP-1 RAs "markedly" inhibit intestinal motility, even in healthy patients without type 2 diabetes.[162]

160. GLP-1 RAs can cause impaired digestion that can manifest as several forms of injury, including gastroparesis, ileus, debilitating cyclical vomiting for days and weeks requiring hospitalization, and intestinal obstruction.

161. Defendants knew or should have known of the risks of gastroparesis, ileus, intestinal obstruction, and their sequelae from the relevant clinical trials, medical literature, and adverse event reports.

162. Defendants' evaluation of gastrointestinal risks during clinical trials was inadequate, and despite mounting postmarketing evidence—discussed below—regarding the gastrointestinal risks associated with GLP-1 RAs, Defendants repeatedly failed to take steps necessary to re-analyze clinical trial data to assess the gastrointestinal side effects of GLP-1 RAs.

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[159] Camilleri, *Prevalence and variations in gastric emptying delay in response to GLP-1 receptor agonist,* Obesity (2023).

[160] Halawi, *et al., Effects of liraglutide on weight, satiation, and gastric functions in obesity: a randomised, placebo-controlled pilot trial,* 2 Lancet 898 (2017) (noting "persistent slowing of gastric emptying of solids at 16 weeks of treatment, despite tachyphylaxis.").

[161] Näslund, *et al., Glucagon-like peptide 1 analogue LY315902: effect on intestinal motility and release of insulin and somatostain,* 106 Regul. Pept. 89 (2002).

[162] Thazhath, *et al., The glucagon-like peptide 1 receptor agonist exenatide inhibits small intestinal motility, flow, transit, and absorption of glucose in healthy subjects and patients with type 2 diabetes: a randomized controlled trial,* 65 Diabetes 269 (2016).

163. There are three validated methods to assess gastric emptying of solids: gastric emptying scintigraphy, the stable isotope gastric emptying breath test, and the wireless motility capsule.[163] However, "gastric emptying of liquids is often preserved in gastroparesis." Thus, "liquids may empty normally" even with gastroparesis. For that reason, gastric emptying studies "based on a liquid challenge result in decreased sensitivity in the diagnosis of gastroparesis."[164]

164. Despite a plethora of evidence, consistent with the drugs' mechanism of action, that GLP-1 RAs affect motility, neither Novo nor Lilly assessed gastric emptying of solids during their clinical trials.[165] Rather than doing so, both companies used the acetaminophen absorption test to assess for emptying of liquids, which is often preserved in gastroparesis patients. As a result, Defendants' clinical trials for their GLP-1 RAs were not adequately designed to assess for gastroparesis.[166]

165. Dr. Michael Nauck, a clinical researcher of GLP-1 RAs and a member of advisory boards for both Lilly and Novo, has acknowledged that clinical trials for GLP-1 RAs measured gastric emptying with the acetaminophen absorption test, which "has substantial limitations including poorly validated assumptions about its absorption kinetics and its unsuitability to measure gastric emptying of solids." He has further acknowledged that, in clinical trials, gastric emptying was often assessed "solely by participant self-report, which is unreliable." He concluded

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[163] Sheng, *Management of Gastroparesis,* Gastroenterology & Hepatology (Nov. 2021).

[164] Camilleri, *Clinical Guideline: Management of Gastroparesis,* Am. J. of Gastroenterology (Jan. 2013).

[165] [redacted]

[166] *See* Goodman, *People using popular drugs for weight loss, diabetes are more likely to be diagnosed with stomach paralysis, studies find,* CNN (May 20, 2024), available at https://www.cnn.com/2024/05/20/health/glp-1-drugs-stomach-paralysis/index.html.

that, "[i]n clinical trials, GI symptoms should be evaluated by validated instruments. Measurement of gastric emptying, using a precise technique, should be a mandatory component of approval packages for GLP-1 RAs."[167]

166. In 2008, the New England Journal of Medicine noted that "serious complications" reported as adverse events for the GLP-1 RA exenatide included "suspected ileus."[168]

167. In a May 2008 case report published in the New England Journal of Medicine, a patient developed "severe gastroparesis," confirmed by a gastric emptying study, after eleven months of exenatide use. She also developed a bezoar, which was removed endoscopically. Exenatide was discontinued, and the patient was treated and improved. Three months after exenatide was re-started, symptoms returned and the patient had a second bezoar removed from her stomach. A follow-up gastroduodenoscopy performed five months after stopping the drug a second time revealed retained food, and the patient was treated with botulinum toxin injected into the pylorus.[169] This dechallenge/rechallenge case presents strong evidence of a causal association between GLP-1 RAs and gastroparesis.

168. In 2011, a gastroenterologist at the Mayo Clinic recognized that drugs such as GLP-1 RAs can cause iatrogenic gastroparesis due to pharmacologic blockage of the vagal nerve.[170]

169. In 2012, the Journal of the Japan Diabetes Society published two case reports of

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[167] Jalleh, *et al*., *Accurate measurements of gastric emptying and gastrointestinal symptoms in the evaluation of glucagon-like peptide-1 receptor agonists*, 176 Ann. Intern. Med. 1542 (2023).

[168] Ahmad, *et al*., *Exenatide and Rare Adverse Events*, 358 New Eng. J. Med. 1969-1972 (May 2008), available at https://www.nejm.org/doi/full/10.1056/nejmc0707137#:~:text=In%20patients%20with%20gastroparesis%2C%20exenatide,in%20patients%20during%20exenatide%20treatment.

[169] Cure, *Exenatide and rare adverse events*, 358 NEJM 1969 (2008).

[170] Camilleri, *et al*., *Epidemiology, Mechanisms, and Management of Diabetic Gastroparesis*, Clinical Gastroenterology and Hepatology Vol. 9, No. 1 (2011). Lilly has likewise recognized the ability of drugs to induce gastroparesis. *See* LL Y-GLPMDL-08196268.

"transient paralytic ileus caused by the administration of Liraglutide." In both cases, the patients "recovered spontaneously after the cessation of Liraglutide." The authors concluded that "physicians and patients should be aware of this serious side effect."[171]

170. In 2012, Japan's Pharmaceutical and Food Safety Bureau advised that "[i]ntestinal obstruction may occur" in patients taking the GLP-1 RAs exenatide and liraglutide, and as a result "[p]atients should be carefully monitored, and if any abnormalities including severe constipation, abdominal distention, persistent abdominal pain, or vomiting are observed, administration of [the drugs] should be discontinued, and appropriate measures should be taken." The agency further reported that in the previous 1 year and 8 months, three cases of intestinal obstruction had been reported in liraglutide users "for which causality [associated with] the drug could not be ruled out." At least one of those patients was diagnosed with ileus.[172]

171. A 2013 article by a co-author who had participated on Novo advisory boards, explained that "[a]cute, intravenous infusion of GLP-1 (in pharmacological doses) slows gastric emptying markedly in both healthy subjects and patients with type 2 diabetes in a dose-dependent manner by mechanisms that include relaxation of the proximal stomach, reduction of antral and duodenal motility, and an increase in pyloric tone, and which involve vagal pathways."[173]

172. In 2013, the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) received a "safety communication from the Japanese medicines

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[171] Kitamura, *et al*., *Two cases of paralytic ileus associated with the administration of liraglutide,* 55 Japan Diab. Soc. 982 (2012).

[172] Pharmaceuticals and Medical Devices Safety Information No. 291, Pharmaceutical and Food Safety Bureau (June 2012), available at https://www.pmda.go.jp/files/000153459.pdf.

[173] Marathe C, *Relationships Between Gastric Emptying, Postprandial Glycemia, and Incretin Hormones*, 36(5) Diabetes Care, 1396-1405 (April 13, 2013), available at https://diabetesjournals.org/care/article/36/5/1396/29534/Relationships-Between-Gastric-Emptying.

agency … reporting intestinal obstruction in patients treated with" GLP-1 RAs. As a result, PRAC searched EudraVigilance "for intestinal obstruction and related terms" and retrieved 59 cases for the GLP-1 RAs exenatide and liraglutide, leading PRAC to recommend appropriate amendments to the product information. EMA reported intestinal obstruction in 35 cases for exenatide and 24 for liraglutide.[174]

173. A 2016 trial funded by Novo measuring semaglutide and cardiovascular outcomes in patients with type 2 diabetes found more gastrointestinal disorders in the semaglutide group than in the placebo group, including a severe adverse event report of impaired gastric emptying with semaglutide 0.5 mg together with other serious gastrointestinal adverse events such as abdominal pain (upper and lower), intestinal obstruction, change of bowel habits, vomiting, and diarrhea.[175]

174. Two subjects in a semaglutide trial pool by Novo reported moderate adverse events of impaired gastric emptying and both subjects permanently discontinued treatment due to the adverse events. Three subjects also reported mild adverse events of impaired gastric emptying in the semaglutide run-in period of trial 4376. The cardiovascular outcomes trials included two cases of gastroparesis, with the first subject being diagnosed with severe gastroparesis after one month in the trial and the second subject being diagnosed with gastroparesis after approximately two months in the trial.

175. A study published in 2017 evaluated the effect of GLP-1 RAs on gastrointestinal

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[174] European Medicine Agency, Pharmacovigilance Risk Assessment Committee, minutes of meeting (January 7-10, 2013) available at https://www.ema.europa.eu/en/documents/minutes/minutes-prac-meeting-7-10-january-2013_.pdf.

[175] Marso, *et al*., *Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes*, N. Eng. J. Med. 375:1834-1844 (November 2016), available at https://www.nejm.org/doi/10.1056/NEJMoa1607141.

tract motility and residue rates and explained that "GLP-1 suppresses gastric emptying by inhibiting peristalsis of the stomach while increasing tonic contraction of the pyloric region." The study authors concluded that the GLP-1 RA drug liraglutide "exhibited gastric-emptying delaying effects" and "the drug also inhibited duodenal and small bowel movements at the same time."[176]

176. Another study in 2017 reviewed the survey results from 10,987 patients and 851 physicians and found that "GI-related issues were the top two patient-reported reasons for GLP-1 RA discontinuation in the past 6 months, with 'Made me feel sick' as the most frequently reported reason (64.4%), followed by 'Made me throw up' (45.4%)."[177] As explained above, these are symptoms of gastroparesis, ileus, and intestinal obstruction.

177. An April 2018 published case series reported six cases involving upper gastrointestinal problems in liraglutide users:

- In the first case, a 50-year-old female developed "severely delayed gastric emptying" after three months of liraglutide use, and her symptoms improved significantly after discontinuation of liraglutide.
- In the second case, a 48-year-old female was diagnosed with "ineffective esophageal motility" after six months of liraglutide use. Her esophageal motility returned to "normal" after discontinuation of liraglutide.
- In the third case, a 62-year-old female experienced bloating, constipation, and "retained food products in the stomach" after starting liraglutide. After discontinuation of liraglutide, examination revealed "no evidence of ... retained food products in the stomach."
- In the fourth case, a 39-year-old female was started on liraglutide, and five months later she underwent a preoperative endoscopy, which "revealed a large amount [of] retained food in the stomach, despite having nothing by mouth for

[176] Nakatani, *et al*., *Effect of GLP-1 receptor agonist on gastrointestinal tract motility and residue rates as evaluated by capsule endoscopy*, 43(5) Diabetes & Metabolism, 430-37 (October 2017), available at https://www.sciencedirect.com/science/article/pii/S1262363617301076.

[177] Sikirica, *et al*., *Reasons for discontinuation of GLP1 receptor agonists: data from a real-world cross-sectional survey of physicians and their patients with type 2 diabetes*, 10 Diabetes Metab. Syndr. Obes., 403-412 (September 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5630073.

more than 12 h." One month after discontinuing liraglutide, a gastric emptying study came back "normal."

- In the fifth case, nine months after starting liraglutide, a 49-year-old female was found to have "a slight decrease in primary esophageal peristalsis," which had returned to normal two weeks after discontinuing liraglutide.

- In the sixth case, a 55-year-old female started liraglutide and was referred for bariatric surgery. A preoperative endoscopy showed "significant retained food in the body and antrum of the stomach." After discontinuing liraglutide for 2 weeks, a solid gastric emptying study revealed gastric emptying in the normal range.

The authors concluded that, "[w]hile liraglutide is known to cause gastric dysmotility," these case reports indicate that GLP-1 RAs also contribute to esophageal dysmotility, as "[i]n all cases" the patients' esophageal dysmotility and/or delayed gastric emptying "improved following discontinuation." The authors also concluded that, on the strength of current medical knowledge, "Liraglutide should ... be considered as a culprit in any patient found to have gastroparesis" and that this effect on gastric emptying "appears to be a GLP-1 class effect" affecting some patients (delayers) but not others (non-delayers).[178]

178. A 2019 study of GLP-1 RA exenatide found that, out of 20 patients without pre-existing gastroparesis, 15 became "gastroparetic after initiation of exenatide therapy," while the other 5 patients without preexisting gastroparesis experienced a moderate increase in gastric half-emptying time. Notably, the researchers used the stable isotope gastric emptying breath test to measure gastric emptying, rather than gastric scintigraphy.[179]

179. A 2019 study of the GLP-1 RA drug dulaglutide identified adverse events for

[178] Modi, *et al., Liraglutide effects on upper gastrointestinal investigations: implications prior to bariatric surgery,* 28 Obes. Surg. 2113 (2018).

[179] Beti, *et al., Exenatide Delays Gastric Emptying in Patients with Type 2 Diabetes Mellitus but not in Those with Gastroparetic Conditions,* Horm. Metab. Res. (2019) (first published online Jan 28, 2019).

impaired gastric emptying and diabetic gastroparesis.

180. In a disproportionality analysis first published in May 2020, researchers analyzed adverse events reported in the WHO's worldwide database between January 2007 and January 2008. The researchers found 216 cases of intestinal obstruction reported for GLP-1 RA users, 37 of which were noted as "serious." The researchers "identified a pharmacovigilance signal that suggests a risk of potentially serious intestinal obstruction" associated with these drugs.[180]

181. A case study published in May 2020 reported on a patient who developed symptoms of partial bowel obstruction within one week of initiating dulaglutide. After "two weeks of severe nausea and vomiting, accompanied by four days of diffused abdominal pain," he was admitted to the hospital where he was diagnosed with "partial or evolving small bowel obstruction." The patient deteriorated quickly, with the condition progressing to a full small bowel obstruction, a "life-threatening surgical emergency." The patient underwent a partial resection of his small bowel "due to severe ischemia." The treating physicians were able to rule out all other possible causes and were able to determine that "Trulicity [dulaglutide] was the culprit of this unfortunate case." Dulaglutide was discontinued, and the patient had no signs of bowel obstructions on follow-up. The authors noted that there was a known association between dulaglutide use and small bowel obstruction, with 8 cases reported in 2017, most of which required surgical intervention.[181]

182. In a September 2020 article funded and reviewed by Novo, scientists affiliated with Novo reported on two global clinical trials that evaluated the effect of semaglutide in patients with cardiovascular events and diabetes. More patients permanently discontinued taking oral

[180] Gudin, *et al.*, *Incretin-based drugs and intestinal obstruction: a pharmacovigilance study*, 75(6) Therapies 641-47 (November-December 2020).

[181] Gandhi, *et al.*, *Dulaglutide Commonly Known as Trulicity; An Anti-diabetic Medication Causing Small Bowel Obstruction*, 4 JESOCI A309 (2020).

semaglutide (11.6%) than placebo (6.5%) due to adverse events. The most common adverse events associated with semaglutide were nausea (2.9% with semaglutide versus 0.5% with placebo), vomiting (1.5% with semaglutide versus 0.3% with placebo), and diarrhea (1.4% with semaglutide versus 0.4% with placebo). Injectable semaglutide had a discontinuation rate of 11.5-14.5% (versus 5.7-7.6% with placebo) over a two-year period. The authors acknowledged the potential for severe gastrointestinal events, warning that "[f]or patients reporting severe adverse gastrointestinal reactions, it is advised to monitor renal function when initiating or escalating doses of oral semaglutide." For patients with other comorbidities, the study warned that "patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-1 RAs." The study further identified as one "key clinical take-home point" that "patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-1 RAs."[182]

183. In November 2020, a case report was published where an 18-year-old female presented to the emergency room with vomiting and upper abdominal discomfort after recently starting a high dose of liraglutide. On examination, she had a distended abdomen and was ultimately diagnosed with "liraglutide-induced gastroparesis." After cessation of liraglutide, "her symptoms resolved completely." The authors attributed the patient's gastroparesis to the high dose of liraglutide and recommended that "[p]atients exhibiting gastroparesis symptoms after taking liraglutide medication must be closely monitored" because "symptomatic gastroparesis can be triggered by the initiation of liraglutide."[183]

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[182] Mosenzon and Warren, *Oral semaglutide in patients with type 2 diabetes and cardiovascular disease, renal impairment, or other comorbidities, and in older patients*, Postgraduate Medicine (2020), 132:sup2, 37-47, available at https://doi.org/10.1080/00325481.2020.1800286 (last visited 9/26/23).

[183] Almustanyir, *Gastroparesis With the Initiation of Liraglutide: A Case Report*, Cureus (Nov. 28, 2020) (https://doi.org/10.7759/cureus.11735).

184. A 2021 retrospective review of upper endoscopies found that patients taking GLP-1 RAs 4.3-fold increased risk of retained gastric contents, which is associated with delayed gastric emptying.[184]

185. A May 2021 meta-analysis found an increased risk of impaired gastric emptying among GLP-1 RA users.[185]

186. A July 2021 article funded and reviewed by Novo considered 23 randomized control trials conducted across the United States, Japan, and China and concluded that "gastrointestinal disturbances" were "well-known" side effects associated with semaglutide use. When compared with placebos, the subcutaneous (injection) form of the drug induced nausea in up to 20% of patients (versus up to 8% on the placebo group), vomiting in up to 11.5% of patients (versus up to 3% in the placebo group) and diarrhea in up to 11.3% of patients (versus up to 6% in the placebo group). Overall, the percentage of patients experiencing adverse events that led to trial product discontinuation was greatest for gastrointestinal related adverse events, with some trials experiencing 100% discontinuation due to gastrointestinal related adverse events. The mean value of gastrointestinal related adverse events that led to discontinuation averaged 57.75%. The study acknowledges that while nausea and vomiting are unwanted side effects, "they may be partly responsible for aspects of the drug's efficacy[.]"[186]

187. An October 2021 case report in the Journal of Investigative Medicine ("JIM")

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[184] Bi, *et al.*, *Food Residue During Esophagogastroduodenoscopy Is Commonly Encountered and Is Not Pathognomonic of Delayed Gastric Emptying*, 66 Digestive Diseases and Science 2951, 3955 (2021).

[185] Yin, *et al.*, *Comprehensive analysis of the safety of semaglutide in type 2 diabetes: a meta-analysis of the SUSTAIN and PIONEER trials*, 68 Endocr. J. 739 (2021).

[186] Smits and Van Raalte (2021), *Safety of Semaglutide*, Front. Endocrinol., 07 July 2021, doi: 10.3389/fendo.2021.645563, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8294388/.

concluded that because gastroparesis can be associated with several medications, "[i]t is crucial to identify the causative drugs as discontinuation of the drug can result in resolution of the symptoms[.]" In diabetics, making this determination can be particularly "tricky" because both diabetes and GLP-1 RAs can cause delayed gastric emptying. As such, "the timeline of drug initiation and symptom onset becomes of the upmost importance." The authors reviewed two case reports (discussed below) and concluded that history taking and making an accurate diagnosis of diabetic gastroparesis versus medication-induced gastroparesis are critical.[187]

188. Case Report #1 in JIM involved a 52-year-old female with long-standing (10 years), well-controlled type 2 diabetes who had been taking weekly semaglutide injections approximately one month prior to the onset of gastroparesis symptoms. The patient was referred with a 7-month history of post-prandial epigastric pain, accompanied by fullness, bloating, and nausea. A gastric emptying study showed a 24% retention of isotope in the patient's stomach at four hours, indicative of delayed gastric emptying. The patient discontinued semaglutide, and her symptoms resolved after six weeks. The case report authors concluded that "thorough history taking revealed the cause [of gastroparesis] to be medication induced."[188]

189. Case Report #2 in JIM involved a 57-year-old female with a long-standing (16 years) type 2 diabetes who had been taking weekly dulaglutide injections (another GLP-1 RA) for 15 months and suffering from abdominal bloating, nausea, and vomiting for 12 of those months. A gastric emptying study showed 35% retention of isotope in the patient's stomach at four hours, indicating delayed gastric emptying. After discontinuing dulaglutide, the patient experienced a

[187] Kalas, *et al*., *Medication-Induced Gastroparesis: A Case Report*, J. Investig. Med. High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/.

[188] *Id*.

gradual resolution of symptoms over a four-week period.[189]

190. A large population-based study published in January 2022 concluded that GLP-1 RAs were associated with an increased risk of intestinal obstruction compared with SGLT-2 inhibitors (1.9 vs. 1.1 per 1,000 person-years, respectively; HR:1.69, 95% CI: 1.04–2.74).[190]

191. A June 2022 study reported GLP-1 RA Mounjaro (tirzepatide) adverse events of vomiting, nausea, and "severe or serious gastrointestinal events."[191]

192. In July 2022, a case report was published of gastroparesis, with symptoms beginning a mere four days after initiation of low-dose liraglutide. The patient's symptoms resolved within days of discontinuing liraglutide. The authors concluded that gastroparesis "is a known serious side effect of GLP-1 agonist treatment," that "[p]hysicians should be cognizant of the side effects of GLP-1 agonists even in low dose in patients who have gastric emptying symptoms suggesting GP," and that the risk of developing gastroparesis "should be considered before initiating GLP-1 agonists in general."[192]

193. An August 2022 meta-analysis an increased risk of impaired gastric emptying among GLP-1 RA users.[193]

194. That same month, the Teikyo Medical Journal published a case report of a 29-year-old male who developed "nausea, vomiting, abdominal bloating, and constipation, starting one day

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[189] *Id*.

[190] Faille, *et al*., *Incretin-based drugs and risk of intestinal obstruction among patients with type 2 diabetes,* 111 Clin. Pharmacol. Ther. 272 (2021).

[191] Jastreboff, *Tirzepatide Once Weekly for the Treatment of Obesity*, N Engl J Med, at 214 (June 4, 2022) (https://doi.org/10.1056/nejmoa2206038).

[192] Ishihara, *Suspected Gastroparesis With Concurrent Gastroesophageal Reflux Disease Induced by Low-Dose Liraglutide*, Cureus (Jul. 16, 2022) (https://doi.org/10.7759/cureus.26916).

[193] Wang et al., *Meta-analysis of the association between new hypoglycemic agents and digestive diseases,* 101 Medicine (Baltimore) (2022).

after a single injection of semaglutide." "The patient became unable to take anything by mouth" and was admitted to the hospital, where an oral-enhanced abdominal CT-Scan revealed gastric dilatation and delayed gastric emptying with no evidence of mechanical obstruction. The patient was diagnosed with "semaglutide induced gastric outlet obstruction with euglycaemic ketosis." With conservative treatment, the patient improved, and two months after discontinuing semaglutide, the patient was symptom free.[194]

195. An October 2022 study analyzed 5,442 semaglutide adverse gastrointestinal events: 32% were serious, including 40 deaths, 53 life-threatening conditions, and 772 hospitalizations. The primary events were nausea and vomiting. The study also found a statistically significant increased rate of impaired gastric emptying reports associated with semaglutide use, compared to the overall rate of reports in the FDA's database.[195]

196. A January 2023 meta-analysis of GLP-1 RA (Mounjaro) adverse events reported high rates of nausea and vomiting.[196]

197. A single-center study published in January 2023 found an increased risk of gastroparesis among GLP-1 RA patients.[197]

198. It was widely reported in the media that, in January 2023, Trish Webster, a woman without diabetes, died while taking Saxenda, after switching from Ozempic. She began using GLP-

[194] Shemies, *et al*., *Semaglutide induced gastric outlet obstruction: a case report,* 45 TMJ 6743 (2022).

[195] Shu, *Gastrointestinal adverse events associated with semaglutide: A pharmacovigilance study based on FDA adverse event reporting system*, Front. Public Health (Oct. 20, 2022). (https://doi.org/10.3389%2Ffpubh.2022.996179).

[196] Mirsha, *Adverse Events Related to Tirzepatide*, J. of Endocrine Society (Jan. 26, 2023) (https://doi.org/10.1210%2Fjendso%2Fbvad016).

[197] Kalas, *et al*., *Frequency of glp-1 receptor agonists use in diabetic patients diagnosed with delayed gastric emptying and their demographic profile*, 71 J. Investig. Med. 11 (2023).

1 RAs to lose weight prior to her daughter's wedding. However, she developed persistent vomiting, diarrhea, and nausea and, on January 16, 2023, she was found unconscious and not breathing by her husband.[198]

199. In February 2023, a longitudinal study of GLP-1 RA (dulaglutide) reported adverse events for nausea and vomiting, and one adverse event of impaired gastric emptying.[199]

200. A February 2023 case series of 100 patients undergoing endoscopy found that 4 out for 23 patients treated with GLP-1 RAs had developed "moderately large" bezoars of 4cm or greater in diameter, while no patients who were not on the drugs had developed bezoars.[200]

201. On March 28, 2023, a case study concluded that impaired gastric emptying is "a significant safety concern, especially since it is consistent with the known mechanism of action of the drug."[201]

202. In a May 2023 letter to the editor published in Acta Pharmaceutica Sinica B, the authors commented on GLP-1 RAs, including Ozempic, Wegovy and Rybelsus, and noted "adverse events such as increased risk of intestinal obstruction have been reported in diabetic

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[198] *See Ozempic risk: could weight loss injections be fatal?*, 60 Minutes Australia (Nov. 5, 2023), *available at* https://www.youtube.com/watch?v=3nvoumJsjus; Amelia Neath, *Woman dies after taking Ozempic to lose weight for daughter's wedding,* Independent (Nov. 10, 2023), *available at* https://www.independent.co.uk/news/world/americas/australia-woman-dies-ozempic-weight-loss-b2445052.html; Adriana Diaz, *Woman dies after taking Ozempic to slim down for daughter's wedding: 'She shouldn't be gone',* New York Post (Nov. 6, 2023), *available at* https://nypost.com/2023/11/06/lifestyle/woman-dies-after-taking-ozempic-to-slim-down-for-wedding/.

[199] Chin, *Safety and effectiveness of dulaglutide 0.75 mg in Japanese patients with type 2 diabetes in real-world clinical practice: 36 month postmarketing observational study*, J Diabetes Investig (Feb. 2023) (https://doi.org/10.1111%2Fjdi.13932).

[200] Preda, *et al.*, *Gastroparesis with bezoar formation in patients treated with glucagon-like peptide-1 receptor agonists: potential relevance for bariatric and other gastric surgery*, 7 BJS Open, 1 (2023).

[201] Klein, *Semaglutide, delayed gastric emptying, and intraoperative pulmonary aspiration: a case report*, Can J. Anesth (Mar. 28, 2023) (https://doi.org/10.1007/s12630-023-02440-3).

patients, which is 4.5 times higher than those receiving other glucose control medications" based on a study published in 2020. The authors further noted a study published in 2022 "of 25,617 subjects demonstrated a 3.5-fold increase in the intestinal obstruction rate associated with GLP-1 RA treatment."[202]

203. In May 2023, the risk of intestinal obstruction was specifically cited in the Lu study, concluding that the use of GLP-1 RAs may result in continuous increases in intestinal length, causing the intestines to "become as inelastic and fibrotic as a loose spring." The study indicated that intestinal blockage peaked after using GLP-1 RAs for a year and a half, which the authors noted was longer than the duration of most clinical studies involving GLP-1 RAs.[203]

204. In June 2023, a case report was published in the British Journal of Anesthesia regarding a tirzepatide patient undergoing hysteroscopy with polyp resection. Although the patient had "appropriately fasted" prior to the procedure, she aspirated a large volume of undigested food during the procedure. The authors recommended revised guidelines for GLP-1 RA patients undergoing anesthesia due to the risks posed by undigested food remaining in patients' stomachs during surgery.[204] In a second case report published that same month, authors similarly reported that a patient on semaglutide, who had appropriately fasted and had no traditional risk factors for

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[202] Lu, *et al*., *A Potentially Serious Adverse Effect of GLP-1 Receptor Agonists*, 13(5) Acta Pharmaceutica Sinica B, 2291-2293 (May 2023), available at https://www.sciencedirect.com/science/article/pii/S2211383523000679; *see also* Faillie, *et al*., *Incretin-Based Drugs and Risk of Intestinal Obstruction Among Patients with Type 2 Diabetes*, Clinical Pharmacology Therapeutics vol. 11, Issue 1 (Jan. 2022), *available at* https://doi.org/10.1002/cpt.2430; Gudin, *et al*., *Incretin-based drugs and intestinal obstruction: a pharmacovigilance study*, 75(6) Therapies 641-47 (November-December 2020).

[203] Lu, *et al*., *A Potentially Serious Adverse Effect of GLP-1 Receptor Agonists*, 13(5) Acta Pharmaceutica Sinica B, 2291-2293 (May 2023), available at https://www.sciencedirect.com/science/article/pii/S2211383523000679.

[204] Weber, *et al*., *Clinically significant emesis in a patient taking a long-acting glp-1 receptor agonist for weight loss,* Br. J. Anaesth. e37 (2023).

regurgitation or aspiration, had regurgitated a large volume of gastric contents upon induction of general anesthesia. Authors cautioned that "[p]atients taking long-acting GLP-1 RAs such as semaglutide may be at risk of pulmonary aspiration under anesthesia."[205]

205. On June 29, 2023, the American Society of Anesthesiologists ("ASA") warned that patients taking semaglutide and other GLP-1 RAs should stop the medication at least a week before elective surgery because these medications "delay gastric (stomach) emptying" and "the delay in stomach emptying could be associated with an increased risk of regurgitation and aspiration of food into the airways and lungs during general anesthesia and deep sedation." The ASA also warned that the risk is higher where patients on these medications have experienced nausea and vomiting.[206]

206. News sources have identified the potential for serious side effects in users of Ozempic, including gastroparesis, leading to hospitalization.[207] For example, NBC News reported

[205] Gulak, *et al*., *Regurgitation under anesthesia in a fasted patient prescribed semaglutide for weight loss: a case report*, 70 Can. J. Anaesth. 1397 (2023); *see also* Fujino, *et al*., *Anesthesia considerations for a patient on semaglutide and delayed gastric emptying*, Cureus (2023) ("[R]egular fasting guidelines may not be adequate to prevent the risk of perioperative aspiration" among semaglutide users.).

[206] American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 29, 2023), available at https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery.

[207] Penny Min, *Ozempic May Cause Potential Hospitalizations*, healthnews (June 26, 2023), available at https://healthnews.com/news/ozempic-may-cause-potential-hospitalizations/; Elizabeth Laura Nelson, *These Are the 5 Most Common Ozempic Side Effects, According to Doctors*, Best Life (April 3, 2023), available at https://bestlifeonline.com/ozempic-side-effects-news/; Cara Shultz, *Ozempic and Wegovy May Cause Stomach Paralysis in Some Patients*, People (July 26, 2023), available at https://people.com/ozempic-wegovy-weight-loss-stomach-paralysis-7565833; CBS News Philadelphia, *Popular weight loss drugs Ozempic and Wegovy may cause stomach paralysis, doctors warn* (July 23, 2023), available at https://www.cbsnews.com/philadelphia/news/weight-loss-drugs-wegovy-ozempic-stomach-paralysis/.

in January 2023 that some Ozempic users were discontinuing use because their symptoms were unbearable, and one user said that five weeks into taking the medication she found herself unable to move off the bathroom floor because she had "vomited so much that [she] didn't have the energy to get up."[208] CNN reported in July that one Ozempic user diagnosed with gastroparesis vomits so frequently that she had to take a leave of absence from her teaching job.[209]

207. A July 25, 2023, article in Rolling Stone magazine—"*Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell*'"—highlighted three patients who have suffered debilitating gastrointestinal related events, including gastroparesis, as a result of their use of GLP-1 RAs. Patient 1 (female, age 37) reported incidents of vomiting multiple times per day and being unable to eat. The patient's physician diagnosed her with severe gastroparesis and concluded that her problems were caused and/or exacerbated by her use of a GLP-1 RA medication. Patient 2 (female) used Ozempic for one year and reported incidents of vomiting, including multiple times per day. The patient's physician diagnosed her with severe gastroparesis related to her Ozempic use. Patient 3 (female, age 42) experienced severe nausea both during and after she discontinued use of a GLP-1 RA. In a statement to Rolling Stone, Novo acknowledged that "[t]he most common adverse reactions, as with all GLP-1 RAs, are gastrointestinal related." Novo further stated that while "GLP-1 RAs are known to cause a delay in gastric emptying, … [s]ymptoms of delayed gastric emptying, nausea and vomiting are listed as side effects." Novo did not claim to have warned consumers about gastroparesis, ileus, intestinal obstruction, and their

[208] Bendix and Lovelace, *What it's like to take the blockbuster drugs Ozempic and Wegovy, from severe side effects to losing 50 pounds*, NBC News (Jan. 29, 2023), available at https://www.nbcnews.com/health/health-news/ozempic-wegovy-diabetes-weight-loss-side-effects-rcna66493.

[209] Goodman, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed*, CNN (July 25, 2023), available at https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis/index.html.

sequelae, or other severe or debilitating gastrointestinal issues.[210]

208. On July 25, 2023, CNN Health reported that patients taking Ozempic have been diagnosed "with severe gastroparesis, or stomach paralysis, which their doctors think may have resulted from or been exacerbated by the medication they were taking, Ozempic." Another patient taking Wegovy (semaglutide) suffered ongoing nausea and vomiting, which was not diagnosed, but which needed to be managed with Zofran and prescription probiotics.[211]

209. On July 26, 2023, a New York hospital published an article to its online health blog section "What You Need to Know About Gastroparesis" entitled "Delayed Stomach Emptying Can Be Result of Diabetes or New Weight-Loss Medicines." It was reported that a growing number of gastroparesis cases had been seen in people taking GLP-1 RAs. The article noted that the weight-loss drugs can delay or decrease the contraction of muscles that mix and propel contents in the gastrointestinal tract leading to delayed gastric emptying. One concern raised was that patients and doctors often assume the symptoms of gastroparesis are reflux or other gastrointestinal conditions, meaning it may take a long time for someone to be diagnosed correctly.[212]

210. In an article published on September 29, 2023, Dr. Caroline Apovian, a Professor of Medicine at Harvard Medical School, indicated that "her team had observed ileus in patients who had been prescribed semaglutide well before the FDA's label change [on September 22,

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[210] Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell"*, Rolling Stone (July 25, 2023), available at https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601.

[211] Goodman, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed*, CNN (July 25, 2023), available at https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis/index.html.

[212] *Delayed Stomach Emptying Can Be Result of Diabetes or New Weight-Loss Medicines*, Montefiore Health Blog article (released July 26, 2023), available at https://www.montefiorenyack.org/health-blog/what-you-need-know-about-gastroparesis.

2023].” In the same article, Dr. Dan Azagury, a Medical Director at Stanford University, explained that “ileus is a rare but potentially severe complication. So, we have to inform patients and we have to let them know that if they have these symptoms they need to check in with their physician.”[213]

211. An October 1, 2023 published case series involved three GLP-1 RA users with retained solids despite 10 hours of preoperative fasting. The authors wrote that GLP-1 RA “drug-induced gastroparesis has been confirmed by acetaminophen absorption measurements, carbon-13 urea breath tests, and esophagogastroduodenoscopy.” The authors also stressed the need for physicians to understand the risks associated with retained solids despite preoperative fasting because of the “high morbidity and mortality” associated with perioperative aspiration of gastric contents.[214]

212. In an October 5, 2023 peer-reviewed Research Letter published in the Journal of the American Medical Association (“JAMA”), the authors examined gastrointestinal adverse events associated with GLP-1 RAs used for weight loss in clinical setting and reported that use of GLP-1 RAs compared with use of bupropion-naltrexone was associated with increased risk of pancreatitis, gastroparesis, and bowel obstruction.[215] The study found that patients prescribed GLP-1 RAs were at 4.22 times higher risk of intestinal obstruction and at 3.67 times higher risk of gastroparesis.

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[213] Mammoser, *Ozempic Label Updated to Include Blocked Intestines as Potential Side Effect*, healthline (September 29, 2023), https://www.healthline.com/health-news/fda-updates-ozempic-label-to-include-blocked-intestines-as-potential-side-effect.

[214] Kittner, *et al., Retained gastric contents after adequate fasting associated with glp-1 receptor agonist use*, 13 JBJS Case Connect 1 (2023).

[215] Mohit Sodhi, *et al.*, *Risk of Gastrointestinal Adverse Events Associated with Glucagon-Like Peptide-1 Receptor Agonists for Weight Loss*, JAMA (published online October 5, 2023), available at https://jamanetwork.com/journals/jama/fullarticle/2810542.

213. Also on October 5, 2023, a medical journal reported a case of Mounjaro (tirzepatide) induced ileus. The authors concluded that the case "highlights the dangers of lack of ... monitoring of Mounjaro," especially in "patients who may be more susceptible to the gastrointestinal side effects of Mounjaro," and noted the need to "rais[e] awareness of potential side effects" of the drug "and their severity."[216]

214. In a case report, also published October 5, 2023, authors reported on a patient who developed severe epigastric pressure and abdominal pain shortly after increasing his dose of tirzepatide from 2.5 mg to 5 mg. Abdominal X-ray and CT scans revealed a small bowel obstruction. The authors attributed the obstruction to the effect that GLP-1 RAs have on motility.[217]

215. In another case report published on October 5, 2023, a patient was hospitalized with abdominal pain, nausea, vomiting, and diarrhea three months after initiating liraglutide. Through diagnostic testing, she was found to have a small bowel obstruction (SBO) due to intussusception, "a rare condition in adults where one segment of the bowel telescopes into the adjacent segment, potentially causing intestinal ischemia." The authors noted that "[t]his case highlights the importance of providers being aware of potential adverse effects, including the rare but serious complication of SBO in patients receiving GLP-1 RA therapy." The authors theorized that "inhibition of intestinal motility" caused by GLP-1 RAs plays a role in causing such side effects and recommended that "clinicians should monitor patients for signs of gastrointestinal distress or

[216] Rao, *et al*., *Mounjaro: A Side Effect*, 7 J. Endocrine Soc. A69-70 (Oct.-Nov. 2023), available at https://academic.oup.com/jes/article/7/Supplement_1/bvad114.128/7290694.

[217] Mathew, *et al*., *Tirzepatide associated partial small bowl obstruction: a case report*, 7 J. Endocrine Society A463 (2023).

obstruction and investigate suspected cases promptly for timely management."[218]

216. In a case study published October 9, 2023, the authors reported a case of a 27-year-old female who had been taking tirzepatide for four months. Shortly after an increase in her dosage of tirzepatide, she presented to the emergency department with "severe abdominal pain, nausea, bilious emesis, and watery diarrhea." A CT scan revealed "a high-grade large-bowel obstruction." Despite conservative intervention, the patient deteriorated, and a repeated x-ray indicated that the obstruction was increasing in size. She underwent an emergency "exploratory laparotomy and was noted to have a massively dilated colon" and "[a] firm fecalith in the mid-sigmoid colon." Doctors performed a total abdominal colectomy. After removing the patient's colon, further examination of the colon "showed extensive gangrenous necrosis" in addition to impacted fecal matter. She was discharged two weeks post-surgery. Aside from tirzepatide use, the patient had no other risk factors for bowel obstruction. The authors concluded that "[c]linicians should be aware that Tirzepatide, and other similar drugs, may cause rare yet life-threatening side effects which include an increased risk of bowel obstruction."[219]

217. A retrospective cohort study published in December 2023 noted a "particularly high discontinuation rate for GLP-1 RAs" and concluded that the high rate of discontinuation "was likely due to previously observed factors such as gastrointestinal adverse effects." Compared to other types of second-line treatment for type 2 diabetes, "GLP-1 RAs had the highest observed risk of discontinuation."[220]

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[218] Alqaisi, *et al.*, *GLP-1 RA Therapy And Intussusception: A Case Report Of Bowel Telescoping In An Obese Patient,* SAT675 J. Endocrine Society A67 (2023).

[219] Gordon, *et al.*, *A rare case of a large bowel obstruction due to Tirzepatide,* 164 CHEST 2334A (2023).

[220] Liss, *et al.*, *Treatment Modification After Initiating Second-Line Medication for Type 2 Diabetes,* Am. J. of Managed Care (Dec. 2023) (https://www.ajmc.com/view/treatment-

218. Another case report of semaglutide-associated gastroparesis was published in January 2024. In that case, the gastroenterologist had a high degree of certainty in the diagnosis of gastroparesis, despite the fact that a gastric emptying study was not performed, due to the symptoms and findings on esophagogastrodueodenoscopy. The authors concluded that the significant improvement of the patient's symptoms after discontinuation of semaglutide "highlights the need to recognize medication-induced gastroparesis as a possible diagnosis" among GLP-1 RA users with gastrointestinal symptoms.[221]

219. A systematic review and network meta-analysis published in January 2024 indicated "safety concerns for GLP-1 RAs, especially with high dose administration, regarding gastrointestinal adverse events." Semaglutide, liraglutide, and tirzepatide were all associated with increased rates of nausea, vomiting, and diarrhea. The odds ratios of these gastrointestinal adverse events were higher with increasing doses of GLP-1 RAs.[222]

220. Two large epidemiological studies published in 2024 found statistically significant increased risk of gastroparesis among GLP-1 RA users, offering further confirmation of the causal association between GLP-1 RAs and gastroparesis.[223]

221. Multiple medical reference sources now recognize GLP-1 RAs as a cause of gastroparesis, including Wolters Kluwer's UpToDate, Statpearls, and David Hui, *et al*.'s Approach

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modification-after-initiating-second-line-medication-for-type-2-diabetes).

[221] Chaudhry, *et al*., *Tendency of semaglutide to induce gastroparesis: a case report,* Cureus (2024).

[222] Yao, *et al*., *Comparative effectiveness of GLP-1 receptor agonists on glycaemic control, body weight, and lipid profile for type 2 diabetes: systematic review and network meta-analysis,* BMJ (Jan. 2024) (http://dx.doi.org/10.1136/bmj-2023-076410).

[223] Nathani, *et al*., *Incidence of gastrointestinal side effects in patients prescribed glucagon-like peptide-1 (glp-1) analogs: real-world evidence,* Sa1964 AGA Abstracts S-598 (2024); Mesgun, *et al., Increased risk of de-novo gastroparesis in non-diabetic obese patients on glp-1 receptor agonists for weight loss: a multi-network study,* Sa1961 AGA Abstracts S-596 (2024).

to Internal Medicine (5th ed.), Huppert's Notes Pathophysiology and Clinical Pearls for Internal Medicine (2024 ed.), McCallum *et al*.'s Gastroparesis Pathophysiology, Clinical Presentation, Diagnosis and Treatment (1st ed.).

222. The medical literature listed above is not a comprehensive list, and additional case reports have indicated that GLP-1 RAs can cause gastroparesis and impaired gastric emptying, ileus, intestinal obstruction, and their sequelae.[224]

223. Indeed, there have been numerous cases reported to the FDA's Adverse Events Reporting System ("FAERS") database where GLP-1 RA patients suffered gastroparesis, impaired gastric emptying, ileus, and intestinal obstruction. The FAERS database also indicates that GLP-1 RA users have reported symptoms consistent with gastroparesis, such as vomiting, nausea, abdominal pain, esophageal rupture, gastrointestinal hypomotility, Wernicke's Encephalopathy, and regurgitation and symptoms consistent with ileus or intestinal obstruction, such as fecal vomiting, discolored vomit, intestinal perforation, intestinal resection, intestinal sepsis, and gastrointestinal ischemia. The FAERS database also confirms that some GLP-1 RA users have suffered severe complications, including hospitalization, disability, and death. Although the FAERS database contains thousands of reports of GLP-1 RA users experiencing symptoms consistent with gastroparesis, ileus, and intestinal obstruction, it has been widely recognized that the FAERS database is an incomplete log of adverse event reports, as only a small percentage of adverse events are ever reported to the FDA. Thus, the number of these adverse events is likely

[224] *See, e.g.*, *Liraglutide-induced Acute Gastroparesis*, Cureus (Dec. 28, 2018) (https://doi.org/10.7759%2Fcureus.3791); Guo, *A Post Hoc Pooled Analysis of Two Randomized Trials*, Diabetes Ther (2020) (https://doi.org/10.1007%2Fs13300-020-00869-z); Preda, *Gastroparesis with bezoar formation in patients treated with glucagon-like peptide-1 receptor agonists: potential relevance for bariatric and other gastric surgery*, BJS Open (Feb. 2023) (https://doi.org/10.1093%2Fbjsopen%2Fzrac169).

much higher than reflected in FAERS data.

224. Defendants knew or should have known of the causal association between the use of GLP-1 RAs and the risks of developing gastroparesis, ileus, intestinal obstruction, and their sequelae, but they ignored the causal association. Defendants' actual and constructive knowledge derived from their clinical studies, case reports, medical literature, including the medical literature and case reports referenced in this Complaint.

225. On information and belief, Defendants not only knew or should have known that their GLP-1 RAs cause delayed gastric emptying, resulting in risks of gastroparesis, ileus, intestinal obstruction, and their sequelae, but they may have sought out the delayed gastric emptying effect due to its association with weight loss. For example, a recent study published in 2023 notes that "it has been previously proposed that long-acting GLP-1 RAs could hypothetically contribute to reduced energy intake and weight loss by delaying GE [gastric emptying,]" and the study authors suggested "further exploration of peripheral mechanisms through which s.c. semaglutide, particularly at a dose of 2.4. mg/week, could potentially contribute to reduced food and energy intake."[225]

G. DEFENDANTS WERE ON NOTICE THAT THERE IS REASONABLE EVIDENCE OF CAUSAL ASSOCIATION BETWEEN GLP-1 RAs, RAPID WEIGHT LOSS AND DEEP VEIN THROMBOSIS (DVT)

226. As previously discussed, DVT occurs when a blood clot forms in one of the body's deep veins, typically in the legs.[226]

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[225] Jensterle, *et al.*, *Semaglutide delays 4-hour gastric emptying in women with polycystic ovary syndrome and obesity*, 25(4) Diabetes Obes. Metab. 975-984 (April 2023), available at https://dom-pubs.onlinelibrary.wiley.com/doi/epdf/10.1111/dom.14944.

[226] Though cases involving DVT—and VTE generally—are not yet included as part of the MDL, there is currently an unopposed motion before the JPML to transfer DVT and VTE cases to the Eastern District of Pennsylvania to be included in this MDL. *See In re Glucagon-Like Peptide-1*

227. Defendants knew or should have known of the risks of DVT from the clinical trials, medical literature, and adverse event reports.

228. Since 2010, there have been 448 reports of DVT and related injuries- including thrombosis, PE, venous thrombosis limb, venous thrombosis, venous occlusion, and pelvic venous thrombosis relating to dulaglutide, liraglutide, semaglutide, and tirzepatide submitted to the FAERS, with 226 submitted ***this year*** alone, as of October 16.[227] Of these 448 events reported, 249 required hospitalization, 75 were life-threatening, and 79 resulted in death.[228]

229. Since June 2021, three comprehensive meta-analyses of GLP-1 RA trials have been published showing that GLP-1 RA use is significantly associated with developing DVT. The June 2021 meta-analysis found a nearly 226% increased risk of DVT when taking semaglutide.[229] The December 2021 meta-analysis noted that while there was not an established association between GLP-1 RAs and most cardiovascular diseases, there was a "significant association with certain cardiovascular conditions," including DVT, specifically.[230] Similarly, the May 2024 meta-analysis "identified that use of GLP-1 RAs was associated with–significantly higher risks of 6 kinds of specific diseases, *i.e.*, aortic aneurysm, DVT, haematoma, gastric ulcer haemorrhage, pancreatitis,

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Receptor Agonists (GLP-1 RAs) Prods. Liability Litig., MDL No. 3094, JPML Docket No. 257 (Aug. 21, 2024).

[227] FDA ADVERSE EVENTS REPORTING SYSTEM (FAERS) *Public Dashboard*, https://fis.fda.gov/sense/app/95239e26-e0be-42d9 -a960-9a5f7f1c25ee/sheet/8eef7d83-7945-4091-b349-e5c41ed49f99/state/analysis, U.S FOOD AND DRUG ADMINISTRATION.

[228] *Id.*

[229] Yin, *et al*., *Comprehensive Analysis of the Safety of Semaglutide in Type 2 Diabetes: A Meta-Analysis of the SUSTAIN and PIONEER Trials*, 6 ENDOCR J 68, (2021) https://www.jstage.jst.go.jp/article/endocrj/68/6/68_EJ21-0129/_html/-char/en.

[230] Liao, *et al*., *Three New Categories of Hypoglycaemic Agents and Various Cardiovascular Diseases: A Meta-Analysis*, J. OF CLINICAL PHARMACY & THERAPEUTICS, 639 (Dec. 23, 2021).

and cholecystitisacute."[231]

230. In September 2024, a case report detailed a twenty-year-old man presenting to the emergency room with DVT after three days of pain and swelling in his left leg. The patient had no history of trauma or family history of thromboembolism, but the patient had been taking Mounjaro in the weeks prior to his hospitalization.[232]

231. [redacted][233]

232. As early as 2016, researchers noted the connection between rapid weight loss and VTE, which includes both DVT and PE. The study tracked the weight and VTE instances of a population in Norway over several years, and found "increased risk" of VTE in obese subjects with weight loss.[234] In 2020, researchers once again noted that among obese patients, significant weight "loss is associated with increased risk of unprovoked VTE." Like the 2016 study, the 2020 study tracked the weight and VTE instances in a specific population over nine years; the 2020 study focused on four U.S. communities.[235]

233. These articles establish that by 2016, and again in 2020, researchers have

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[231] Wang, *et al*., *A Comprehensive Meta-Analysis of the Association of SGLT2is and GLP-1 RAs with Vascular Diseases, Digestive Diseases and Fractures*, 61 SPRINGER NATURE 1097, 1102 (May 7, 2024).

[232] Faroqi, *et al*., *Extensive Deep Vein Thrombosis in a Young Man Taking Tirzepatide for Weight Loss*, AACE CLINICAL CASE REPORTS, https://www.sciencedirect.com/science/article/pii/S2376060524000981#bib7 (Sept. 5, 2024)

[233] [redacted]

[234] Horvei, *et al*., *Weight Change and Risk of Venous Thromboembolism: The Trosmo Study*, PLOS ONE (Dec. 20, 2016) https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0168878#abstract0.

[235] French, *et al*., *Weight Change Over 9 Years and Subsequent Risk of Venous Thromboembolism in the ARIC Cohort*, INT'L J. OBESITY (Sept. 18, 2020).

documented the increased risk obese patients face when undergoing rapid and/or significant weight loss,[236] an outcome commonly associated with GLP-1 RAs. As such, Defendants should have been aware of the association between rapid and/or significant weight loss—a notable outcome of GLP-1 RAs—and developing DVT, a serious and potentially life-threatening condition.

234. As stated above, Defendants manufacture drugs that promote significant and rapid weight loss in patient populations either statistically more likely to be obese or obese patient populations specifically: the FDA approved Ozempic, Rybelsus, Trulicity, and Mounjaro to treat people with type 2 diabetes, 90% of whom are obese or overweight.[237] Additionally, FDA approved Wegovy and Zepbound to assist obese or overweight individuals with weight loss and weight management.

235. Defendants' targeted patient populations that include substantial numbers of obese and overweight patients, the precise cohort of people for whom significant and/or extreme weight loss has been shown to increase the risk for developing DVT in multiple studies.[238]

236. Defendants manufacture drugs that induce significant and/or rapid weight loss specifically for the population for whom significant and/or rapid weight loss creates a risk for

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[236] *Id.*; Horvei, *et al*., *Weight Change and Risk of Venous Thromboembolism: The Trosmo Study*, PLOS ONE (Dec. 20, 2016) https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0168878#abstract0.

[237] "90% of people with type 2 diabetes have obesity or are overweight." *Type 2 Diabetes and Metabolic Surgery*, AM. SOC'Y FOR METABOLIC & BARIATRIC SURGERY, https://asmbs.org/resources/type-2-diabetes-and-metabolic-surgery-fact-sheet/#:~:text=Obesity%20%E2%80%93%20medically%20defined%20as%20a,BMI%20of%20at%20least%2025).

[238] Horvei, *et al*., *Weight Change and Risk of Venous Thromboembolism: The Trosmo Study*, PLOS ONE (Dec. 20, 2016) https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0168878#abstract0; see also French, *et al*., *Weight Change Over 9 Years and Subsequent Risk of Venous Thromboembolism in the ARIC Cohort*, INT'L J. OBESITY (Sept. 18, 2020).

developing DVT.[239]

237. The 2020 study considered weight loss of 16.98 pounds or more between doctor's visits nine years apart to be significant.[240] On its website, Novo boasts that patients lose an average of 14.1 pounds in just ten months on Ozempic,[241] demonstrating that this drug induces weight loss at a rate closely associated with increased DVT risk.

238. Defendants knew or should have known about the association between significant weight loss in obese subjects and the increased risk of DVT, and Defendants should have been aware of the risk posed to their target patient population.

239. At all relevant times, Defendants knew or should have known of the association between the use of GLP-1 RAs and the risk of developing DVT, as demonstrated by multiple clinical studies, case reports, and medical literature.

240. Upon information and belief, Defendants knew from their required premarket and post-market research and analytics that GLP1-RAs could cause DVT but failed to take appropriate actions to adequately warn patients of the increased risk of developing DVT.

241. Upon information and belief, Defendants ignored the association between the use of GLP-1 RAs and the risk of developing DVT.

242. Defendants never included a warning of risk of developing DVT on their labels.

243. Defendants not only failed to warn of the risk of DVT in their extensive marketing,

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[239] *Ozempic (Semaglutide) Injection—Compelling Weight Loss Across Doses*, OZEMPIC, https://www.novomedlink.com/diabetes/products/treatments/ozempic/efficacy-safety/ozempic-and-weight.html.

[240] French, *et al*., *Weight Change Over 9 Years and Subsequent Risk of Venous Thromboembolism in the ARIC Cohort*, INT'L J. OBESITY (Sept. 18, 2020).

[241] *Ozempic (Semaglutide) Injection—Compelling Weight Loss Across Doses*, OZEMPIC, https://www.novomedlink.com/diabetes/products/treatments/ozempic/efficacy-safety/ozempic-and-weight.html.

but also promoted the cardiovascular benefits of their medications. Novo specifically mentions on its websites that Ozempic and Wegovy lowers the risk of major cardiovascular events, despite the evidence linking GLP-1 RAs to an increased risk of DVT.[242]

244. Defendants failed to timely disclose to treating physicians the risks of increased risk of DVT associated with GLP-1 RAs.

245. Defendants failed to provide instructions on how to safely use the drug to mitigate harms, including how to safely monitor the patient for adverse effects or how to safely take the patient off the drug without causing a worsening of DVT.

246. Defendants' failure to disclose the known association between GLP-1 RAs and DVT rendered the warnings for these medications inadequate.

247. As a direct and proximate result of Defendants' negligent testing, monitoring, and pharmacovigilance of GLP-1 RAs, Defendants introduced drugs that they knew or should have known would cause serious and severe complications in people, including DVT.

248. Defendants' negligence in testing, monitoring, pharmacovigilance, and providing warnings and instructions regarding GLP-1 RAs has led to severe complications in patients who were prescribed these medications, including significant physical and emotional suffering, and hospitalizations, and even death.

H. DEFENDANTS WERE ON NOTICE THAT THERE IS REASONABLE EVIDNECE OF CAUSAL ASSOCIATION BETWEEN GLP-1 RAs, WEIGHT LOSS AND GALLBLADDER INJURY

249. GLP-1 RAs impact on the gallbladder and biliary system is well-documented and poses significant risks to patients. As previously discussed, GLP-1 RAs delay gastric emptying,

[242] *Ozempic*, https://www.ozempic.com/why-ozempic/what-is-ozempic.html#cardiovascular, OZEMPIC; *Wegovy*, https://www.wegovy.com/about-wegovy/why-wegovy.html#cv-section, WEGOVY.

leading to increased bile stasis within the gallbladder.[243] The reduced contractility of the gallbladder, combined with increased bile concentration, results in an elevated risk of gallstone formation and other gallbladder-related complications, including cholecystitis (inflammation of the gallbladder) and other bile duct and gallbladder diseases.[244]

250. GLP-1 RAs have also been associated with an increased risk of biliary complications, including the accumulation of biliary sludge, which can lead to biliary obstruction and inflammation, often necessitating surgical intervention, such as cholecystectomy (gallbladder removal).[245] This accumulation creates further risks of biliary obstruction and inflammation, conditions that also often necessitate surgical intervention, such as cholecystectomy (gallbladder removal).[246]

251. Defendants knew or should have known of the risks of biliary disease (diseases of the bile tract), specifically gallbladder-related complications, including cholelithiasis (gallstones), cholecystitis (inflammation of the gallbladder), and the need for cholecystectomy (gallbladder removal surgery) from the clinical trials, medical literature (including meta-analyses), and adverse event reports.[247]

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[243] Faillie, *et al*., *Association of Bile Duct and Gallbladder Diseases with the Use of Incretin-Based Drugs in Patients with Type 2 Diabetes Mellitus*, 176 JAMA Internal Med. 1474 (2016) at 3; Nauck, *et al*., *Effects of Liraglutide Compared with Placebo on Events of Acute Gallbladder or Biliary Disease in Patients with Type 2 Diabetes at High Risk for Cardiovascular Events in the LEADER Randomized Trial*, 42 Diabetes Care 1912 (2019) at 1918.

[244] *Id*.

[245] He, *et al*., *Association of Glucagon-Like Peptide-1 Receptor Agonist Use with Risk of Gallbladder and Biliary Diseases: A Systematic Review and Meta-analysis of Randomized Clinical Trials*, 182 JAMA Internal Med. 513 (2022) at 2-3.

[246] *Id*. at 8.

[247] Faillie, *et al*., *Association of Bile Duct and Gallbladder Diseases with the Use of Incretin-Based Drugs in Patients with Type 2 Diabetes Mellitus*, 176 JAMA Internal Med. 1474 (2016) at 12.

252. A meta-analysis published on March 28, 2022, analyzing randomized clinical trials dating back to 2009, found that patients using GLP-1 RAs had a 37% increase in their risk of gallbladder and biliary diseases, including an increased risk of gallstones (cholelithiasis) and inflammation of the gallbladder (cholecystitis), and 70% increase in their risk of cholecystectomy (gallbladder removal surgery).[248] The analysis was performed from August 5, 2021 to September 3, 2021 and involved 76 randomized clinical trials from 2009 to 2021.

253. These 76 randomized clinical trials dating back to 2021 put Defendants on notice of the risks GLP-1 RAs posed to the biliary system and gallbladder. A meta-analysis is "a subset of systematic reviews; a method for systematically combining pertinent qualitative and quantitative study data from several selected studies to develop a single conclusion that has greater statistical power."[249] The conclusion reached by meta-analyses are often "statistically stronger than the analysis of any single study, due to increased numbers of subjects, greater diversity among subjects, or accumulated effects and results."[250]

254. A study published on October 1, 2016 found that "[t]he use of GLP-1 analogues was associated with an increased risk of bile duct and gallbladder disease." [251] The study was specifically designed to assess the impact of certain diabetes drugs, including GLP-1 RAs, on "patients with type 2 diabetes."

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[248] He, *et al*., *Association of Glucagon-Like Peptide-1 Receptor Agonist Use with Risk of Gallbladder and Biliary Diseases: A Systematic Review and Meta-analysis of Randomized Clinical Trials*, 182 JAMA Internal Med. 513 (2022); *see also* Yang, *et al*., *Weight Reduction and the Risk of Gallbladder and Biliary Disease: A Systematic Review and Meta-analysis of Randomized Clinical Trials*, 25 Obesity Rev. e13725 (2024).

[249] https://guides.himmelfarb.gwu.edu/studydesign101/metaanalysis.

[250] *Id*.

[251] Faillie, *et al*., *Association of Bile Duct and Gallbladder Diseases with the Use of Incretin-Based Drugs in Patients with Type 2 Diabetes Mellitus*, 176 JAMA Internal Med. 1474 (2016) at 3.

255. Results of a clinical trial published in August of 2019 showed an increased risk of uncomplicated gallbladder stones, complicated gallbladder stones, cholecystitis, and biliary obstruction with liraglutide.[252] This trial, the LEADER trial, indicated that weight loss and reduced energy intake associated with GLP-1 RAs can lead to gallbladder stasis, increasing cholesterol saturation of bile and contributing to the formation of sludge and gallstones which are mechanisms that are recognized factors in the development of gallstone-related complications and help explain the increased risk of gallbladder- or biliary tract–related events observed with GLP-1 RAs. The study reported higher incidence of cholecystitis and an increased likelihood of patients requiring cholecystectomy for the group using liraglutide compared to those on placebo.[253]

256. In addition, there were continuous yearly increases in the total number of adverse events reported from 2014 to 2022 when the FDA was compelled to release a report from the FAERS database that indicated potential signals of serious risks, exposing patients to unnecessary and preventable risks, injuries, and surgeries.[254]

I. BACKGROUND ON PHARMACEUTICAL MARKETING

1. Regulatory Framework for Pharmaceutical Advertising

257. Pharmaceutical marketing and promotional labeling are regulated by the FDA.

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[252] Nauck, *et al*., *Effects of Liraglutide Compared with Placebo on Events of Acute Gallbladder or Biliary Disease in Patients with Type 2 Diabetes at High Risk for Cardiovascular Events in the LEADER Randomized Trial*, 42 Diabetes Care 1912 (2019) at 1918.

[253] *Id*.

[254] FDA ADVERSE EVENTS REPORTING SYSTEM (FAERS) *Public Dashboard*, https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/8eef7d83-7945-4091-b349-e5c41ed49f99/state/analysis, U.S FOOD AND DRUG ADMINISTRATION. U.S. Food & Drug Admin., Potential Signals of Serious Risks/New Safety Information Identified by the FDA Adverse Event Reporting System (FAERS): April - June 2022 (2022), https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/april-june-2022-potential-signals-serious-risksnew-safety-information-identified-fda-adverse-event (accessed Oct. 15, 2024).

258. By statute, the FDA defines the term "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."[255] The statute contemplates that certain marketing materials are part of the product's labeling: "brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published . . . for use by medical practitioners, pharmacists or nurses containing drug information supplied by the manufacturer, . . . of the drug and which are disseminated by or on behalf of its manufacturer . . . are hereby determined to be labeling as defined in section 201(m) of the act."[256]

259. The FDA recognizes a difference between direct-to-consumer ("DTC") advertisements and promotional labeling.[257] According to the FDA: "DTC ads are published in magazines and newspapers that are distributed to a general audience rather than to healthcare providers such as doctors, nurses, and pharmacists. DTC ads can also be broadcast through television or radio." In contrast to those direct-to-consumer ***advertisements***, the FDA notes: "Other types of materials, such as brochures, booklets, or pamphlets distributed to patients, caregivers, or other non-healthcare providers are considered DTC ***promotions***. While many people would think these are ads, they are technically considered a different category, called promotional labeling."[258]

260. The FDA distinguishes this separate category of "promotional labeling," from

[255] 21 U.S.C. § 321(m).

[256] 21 CFR 202.1(k)(2).

[257] https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms#:~:text=The%20law%20requires%20that%20product,Generic%20Name.

[258] *Id*. (emphasis added).

advertisements: "Promotional labeling and advertising are both used to help sell prescription drugs. Promotional labeling differs from advertising in the way it is distributed. Ads are usually broadcast on TV or radio, or are published in newspapers or magazines. Promotional labeling includes additional types of materials and ways to get them to the consumer. . . ."[259] Importantly, "[p]romotional labeling about a drug is said to 'accompany' that drug, even if the promotional labeling is not physically attached to a drug container. Promotional labeling must be accompanied by the drug's prescribing information.'"[260]

261. Under the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and FDA's implementing regulations, drug promotional labeling and prescription drug advertising must be truthful and non-misleading, convey information about the drug's efficacy and its risks in a balanced manner, and reveal material facts about the drug.[261]

262. FDA guidance indicates that "Firms generally have flexibility with respect to the presentation of efficacy and risk information about their products as long as the presentation is not false or misleading and complies with other applicable statutory and regulatory requirements."[262] Despite that flexibility, the FDA instructs firms that when they develop DTC promotional communications, "they should consider how to best convey information about a drug's efficacy and risks so the audience understands the information."[263]

263. When evaluating communication of the risks in a promotional piece, FDA guidance

[259] https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms#promotional_labeling.

[260] *Id*.

[261] https://www.fda.gov/media/169803/download.

[262] *Id*. (emphasis added).

[263] *Id*.

states that it "looks not just at specific risk-related statements, but at the net impression - i.e., the message communicated by all elements of the piece as a whole."[264] In other words, the FDA recognizes that pharmaceutical marketing must have fair balance defined as:

> law requires that product claim ads give a "fair balance" of information about drug risks as compared with information about drug benefits. This means that the content and presentation of a drug's most important risks must be reasonably similar to the content and presentation of its benefits. This does not mean that equal space must be given to risks and benefits in print ads, or equal time to risks and benefits in broadcast ads. The amount of time or space needed to present risk information will depend on the drug's risks and the way that both the benefits and risks are presented.[265]

264. The definition of "fair balance" is not black and white. Indeed, the FDA recognizes the impact emotion can have on an individual's ability to understand risks or benefits of a drug. For example, in the FDA Evidence Based User Guide for Pharmaceutical Marketing, the FDA notes that "[a]ffect and emotion influence perceptions of likelihood, value, and the risk-benefit balance. These feelings and thoughts interact but also separately predict risk perceptions and decisions. Feelings can limit effective risk communication sometimes, but are often critical to good decision-making; their power can be harnessed in persuasive and non-persuasive communication."[266]

265. The FDA also recognizes the fact that sophisticated marketing techniques influence physician prescribing behavior. This phenomenon is described in draft guidance, where the FDA explains that "[r]esearch demonstrates that promotional communications about medical products often employ marketing techniques that are effective at influencing attitudes and behaviors of

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[264] https://www.fda.gov/media/76269/download (emphasis in original).

[265] https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms#:~:text=The%20law%20requires%20that%20product,Generic%20Name.

[266] https://www.fda.gov/files/about%20fda/published/Communicating-Risk-and-Benefits---An-Evidence-Based-User%27s-Guide-%28Printer-Friendly%29.pdf.

HCPs [("Healthcare Providers")], and that how information is presented can impact HCP impressions of that information. These marketing techniques can influence attitudes and behavior, independent of the quality of the information, even among highly educated medical professionals."[267]

266. The power and influence of marketing, even on healthcare providers, is one reason the FDA forbids "off-label" marketing. Off-label marketing occurs when an FDA-approved drug or device is advertised for a purpose for which it is not approved. It is legal for a physician or other prescriber to prescribe an FDA-approved drug for an off-label use but it is illegal to market those drugs for such off-label use. Promoting or advertising a drug for anything other than its FDA-approved use, the manufacturer is described as illegal "misbranding."[268] When a drug such as Ozempic or Mounjaro is marketed or promoted for weight loss, that is considered off-label marketing and the products are considered "misbranded" under the governing FDA regulations.

267. It is recognized that off-label marketing can harm patients, third-party payors, competitor manufacturers, and researchers and clinicians in multiple ways.[269] This includes the exposure to adverse side effects from drugs that have not been adequately tested for safety and effectiveness in treatment of a particular condition.[270] This can occur when the off-label promotion taps a market demand without spending the time or money to get full safety clearance by the FDA.[271]

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[267] https://www.fda.gov/media/173172/download.

[268] https://pmc.ncbi.nlm.nih.gov/articles/PMC10077121/#bib5.

[269] *Id*.

[270] *Id*.

[271] *Id*.

2. Methods of Pharmaceutical Marketing

268. Pharmaceutical marketing is a sophisticated industry that follows well-established practices. It is typically a well-integrated process, where customers targeted by a manufacturer's marketing receive a seamless experience and consistent messaging through advertising, personal selling, sales promotions, public relations, and branded and unbranded marketing.

269. "Branded" marketing is marketing that directly states the prescription drug name. Branded marketing for prescription drugs is overseen by the FDA and must meet certain requirements. These include requirements that it must not be false or misleading; must have fair balance between efficacy and risk information; and must reveal material facts about the drug being promoted, including facts about the consequences that may result from use of the drug.[272]

270. "Unbranded" campaigns typically contain "help-seeking" advertisements. These advertisements describe a disease or condition – like obesity – but do not recommend a specific drug to treat this condition. Instead, the advertisement directs the patient to speak with their physician. These types of unbranded campaigns are not regulated by the FDA and are not held to the same FDA regulatory oversight.[273] Industry experts recognize that unbranded campaigns can be particularly helpful when focusing on a condition that may be stigmatized or difficult to talk about with a provider.[274]

271. Pharmaceutical marketing is most effective when it utilizes both branded and unbranded campaigns.

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[272] https://www.fda.gov/drugs/office-prescription-drug-promotion/bad-ad-program.

[273] https://www.fda.gov/drugs/prescription-drug-advertising/basics-drug-ads#:~:text=Types%20of%20Advertisements-,Product%20Claim%20Advertisements,significant%20risks%20of%20the%20drug.

[274] https://www.fiercepharma.com/marketing/unbranded-pharma-ad-what-are-they-good-for-actually-quite-a-bit-marketer-panelists-say.

272. Branded and unbranded marketing campaigns can be conducted through a variety of marketing channels. Common channels of pharmaceutical marketing include the use of sales representatives, DTC marketing, advocacy groups, key opinion leaders / speaker programs, social media and online websites, partnerships with telehealth providers and clinicians, television, print and radio advertisements, and coupon programs.

273. Defendants utilize what is known as an Omnichannel marketing scheme. This highly sophisticated marketing scheme has data flow back and forth from each source of advertising in a highly efficient manner to better target health care providers and potential customers.

274. Novo combines this omnichannel strategy and the resulting data pool with the use of algorithms and machine learning to create some of the most powerful pharmaceutical marketing to date. As far back as 2012, Novo discussed the use of algorithms, noting that "[t]he algorithm is able to determine the patient's therapeutic readiness to initiate therapy, determine if they're looking for a change in product, if they just need more help and support in adhering to the therapy they're on. That's a game changer."[275]

275. Novo continues their use of big data and machine learning to create highly effective, targeted marketing campaigns today.[276] This includes the use of predictive mathematical formulas to determine exactly which piece of marketing material should be delivered in which channel and at what time to a particular healthcare provider to maximize prescription rates.[277]

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[275] Patient Marketing Report: From A1C to Z - MM+M - Medical Marketing and Media (mmm-online.com).

[276] https://www.youtube.com/watch?v=nCZR6wK7MlU, Utilizing Advanced Marketing Analytics for Sales Optimization, Peter Vester, Novo Nordisk.

[277] https://www.youtube.com/watch?v=nCZR6wK7MlU, Utilizing Advanced Marketing Analytics for Sales Optimization, Peter Vester, Novo Nordisk.

J. DEFENDANTS EXTENSIVE AND MULTIFACETED MARKETING AND PROMOTION OF GLP-1 RAs

276. After Novo saw the positive weight-loss effect of liraglutide, it began to formulate a new strategy that would increase the long-term financial solvency of the company. To profit from a drug that purports to help with weight loss outside of the diabetes context, Novo sought to fundamentally change the paradigm that doctors and insurers applied to weight-loss treatments. Diet and exercise were long considered the treatment for health weight loss and no insurance company, including Medicare, would reimburse for weight-loss drugs.

277. During the early-2000s, there was substantial dispute as to whether obesity should be classified as a disease rather than a behavioral issue. In 2013, the American Medical Association ("AMA") House of Delegates voted to recognize obesity as a disease state that requires treatment and prevention in 2013. Obesity's classification as a disease opened medical professionals up to considering pharmaceuticals as a possible treatment and opened insurers up to the possibility of reimbursing for that treatment. This change was supported by advocacy organizations associated with Defendants.

278. Novo began intentionally targeting the obesity market in 2012.[278] In its 2012 annual investment report, it listed "establish presence in obesity" as a strategic focus area.[279]

279. Novo's first weight-loss drug was launched in 2014 when the FDA approved liraglutide for the treatment of obesity under the brand name Saxenda.[280] Saxenda, however,

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[278] https://www.annualreports.com/HostedData/AnnualReportArchive/n/NYSE_NVO_2012.pdf slide 18

[279] *Id.*

[280] Kolata, Gina, *We Know Where New Weight Loss Drugs Came From, but Not Why They Work: The empty auditoriums, Gila monsters, resistant pharmaceutical executives and enigmas that led to Ozempic and other drugs that may change how society thinks about obesity*, NY Times (Aug. 17, 2023) available at https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-

required daily injections and its effects on weight loss were modest. From that initial experience, Novo determined there was a large untapped market for weight loss drugs - particularly if they required fewer injections.

280. In an effort to find ways to make a longer-lasting GLP-1 agonist so patients would not have to inject themselves every day, Novo created a new molecule with the chemical name semaglutide.[281] The molecule was marketed under the brand name Ozempic and it was ultimately approved to treat diabetes.

281. Even though it was only approved for diabetes, Novo realized that there was potential to maximize its profits from Ozempic if it could turn Ozempic into an obesity drug. Novo could expand the market for Ozempic and have an endless supply of potential customers that far exceeded any profits it would see from Ozempic's use solely as a diabetes medication.

282. Novo's annual reports to investors and Capital Days presentations repeatedly state that they intend to change the perception of obesity and the way it's treated – to advocate that it must be classified as a disease, covered by insurance, and treated with its weight loss drugs.[282] In 2019, Novo wrote in its investor report that its mission was to "change how the world sees people with obesity and make obesity a healthcare priority";[283] and in its presentation included a

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ozempic-wegovy.html.

[281] *Id*.

[282]https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2020/Novo-Nordisk-Annual-Report-2019.pdf; *see also* Novo Nordisk 2015 Annual Report 28-29, https://www.novonordisk.com/content/dam/Denmark/HQ/Commons/documents/Novo-Nordisk-Annual-Report-2015.PDF (describing Novo's 10-year ambition to educate doctors and make sure that obesity is widely recognized as a disease); Novo Nordisk 2018 Annual Report 26-27, https://www.novonordisk.com/content/dam/nncorp/global/en/about-us/pdfs/corporate-governance/annual-general-meetings/agm2019/uk/annual-report-2018.pdf (detailing Novo's commitment to "making obesity a healthcare priority").

[283] https://www.novonordisk.com/content/dam/nncorp/global/en/investors/pdfs/capital-markets-day/Capital%20markets%20day%202019%20presentation.pdf p. 55

projection showing growth of the weight-loss drug market from approximately 15 million to 24 million patients acknowledging that having obesity recognized as a chronic disease helped increase the market for Novo's GLP-1 RAs.[284]

283. Novo had already worked to have obesity classified as a disease but creating and expanding the market for its weight-loss drugs required a multiprong approach. First, Novo flooded the medical community with money in an effort to change the medical consensus as it relates to treating obesity. This included, among other things, direct payments to physicians, involvement in advocacy organizations, funding research, promoting articles in well-respected journals, and controlling key opinion leaders.

284. As discussed below, Novo used the power of algorithms and machine-learning to target physicians and change prescribing behavior. Novo's efforts included undercutting the well-established health guidance that diet and exercise are key to a healthy weight loss and ultimately sustaining a health weight; and, in its place, pushing a pharmaceutical intervention as the only treatment option that will be successful.

285. Novo invested billions in marketing Ozempic and its other GLP-1 RAs to push Ozempic into the cultural zeitgeist, creating an image as a miracle drug and driving patients to pressure their doctors to prescribe a "weight-loss" drug. That marketing included off-label marketing, pushing Ozempic for weight loss when it was never approved for such an indication (and even Wegovy was not approved until June of 2021).

286. Ozempic's high cost, and the barriers to consumers' access to the drug, presented substantial hurdles to Novo's ability to profit on its GLP-1 RA. Therefore, Novo invested millions in lobbying efforts to ensure funding for consumers who wanted access to the drugs and did

[284] *Id.*

everything it could to broaden such access. For example, Novo first directly partnered with and then directly invested in well-known telemedicine company Noom, ensuring that Novo could sell Ozempic and other GLP-1 RAs to consumers without having to visit a doctor. The key qualifying factors for Wegovy, BMI and an additional confounding health factor, are especially vulnerable to manipulation in the telemedicine context.

287. Even though Lilly lagged behind Novo in introducing a GLP-1 RA, it reaped the benefits of the foundation that Novo laid and joined in the strategy. Lilly made a substantial monetary investment in swaying the medical consensus by making direct payments to physicians and financially supporting or infiltrating numerous healthcare advocacy groups including many of the same groups being supported by Novo; Lilly spent vast sums of money on all forms of advertising and marketing to grow consumer demand; promoting off-label use of Mounjaro; and Lilly spent millions of dollars on lobbying for changes in the law to support broader financial support and access for obesity treatments.

288. Much like Novo, Lilly executives admitted to investors that it: "need[ed] to shift the conversation for people to actually start thinking about obesity as a medical condition."[285] Lilly also understood the market was growing, comparing Mounjaro's launch in 2022 to its prior Trulicity launch noting that "[t]he market has evolved quite a bit and so we will be putting much more horsepower around the launch than what we did with Trulicity."[286] That increase in "horsepower" involved "promoting to around 100,000 physicians for tirzepatide [Mounjaro]" at

[285] Eli Lilly at Morgan Stanley's 20th Annual Global Healthcare Conference (Sep. 13, 2022), https://web.archive.org/web/20221001135415/https://investor.lilly.com/webcasts-and-presentations.

[286] Eli Lilly & Co Conf Presentation Call 2022524 DN000000002983664779.pdf.

launch compared to what was approximately "40,000 physicians for Trulicity."[287]

289. Sales of Novo's GLP-1 RAs Ozempic and Wegovy grew exponentially in 2022 and 2023 with shortages resulting from the huge demand. In August of 2023, Novo reported that in the first six months of 2023, sales of Wegovy soared 344% in the U.S. to nearly $1.7 Billion, while sales of Ozempic jumped 50% to more than $3.7 Billion.[288] The number of prescriptions filled reached what was, at that time, an all-time high of 373,000 in one week in February of 2023, with more than half of those being new prescriptions.[289] In June 2023, it was reported that new prescriptions for Ozempic had surged by 140 percent from the prior year.[290] The latest data shows that between January 2021 and December 2023 prescriptions for semaglutide soared over 442%.[291] In May 2024, CNN published that 1 in 8 adults in the United states has taken Ozempic or another GLP-1 drug.[292]

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[287] Eli Lilly & Co Conf Presentation Call 2022524 DN000000002983664779.pdf.

[288] Woods, Bob, *Big pharma's blockbuster obesity drug battle is just getting started, and it's headed for $100 billion*, CNBC (Sept. 9, 2023) available at https://www.cnbc.com/2023/09/09/big-pharma-blockbuster-obesity-drug-battle-is-headed-for-100-billion.html#:~:text=Novo%20traded%20earnings%20jabs%20with,to%20more%20than%20%243.7%20billion.

[289] Choi and Vu, *Ozempic prescriptions can be easy to get online. Its popularity for weight loss is hurting those who need it most*, CNN (Mar. 17, 2023) available at https://www.cnn.com/2023/03/17/health/ozempic-shortage-tiktok-telehealth/ (last visited on Sept. 18, 2023).

[290] Gilber, Daniel, *Insurers clamping down on doctors who prescribe Ozempic for weight loss: A new class of drugs is causing a public sensation and an industry gold rush, but questions remain about their accessibility to an overweight nation*, Wash. Post (June 12, 2023) available at https://www.washingtonpost.com/business/2023/06/11/weight-loss-ozempic-wegovy-insurance.

[291] Chernikoff, Sara, *Who gets Ozempic? People with private insurance and generous health plans, study shows*, USA Today (Aug. 7, 2024) available at https://www.usatoday.com/story/news/health/2024/08/07/ozempic-semaglutide-access-insurance-study/74692296007/.

[292] McPhillips, Diedre, *1 in 8 adults in the US has taken Ozempic or another GLP-1 drug, KFF*

290. At its Capital Markets Day held on March 7, 2024, where the company provides a progress update on its Strategic Aspirations for 2025, Novo admitted that it had "unlocked the market with Wegovy" noting that sales for "obesity care" had grown from 8 Billion Danish Krone ("DKK") in 2021 (approximately 1.16 Billion USD) to 42 Billion DKK ($6.1 Billion USD) in 2023. Over 75% of those sales were Wegovy with Saxenda making up the remainder. Novo admitted that its current aspiration is to "[c]ontinue efforts to expand the market by reaching more patients and establish obesity as a serious chronic disease."[293]

291. Lilly's efforts also paid off: Mounjaro, which only received FDA approval on May 13, 2022, "generated $5.2 billion in 2023" and "Zepbound, the same molecule rebadged for the weight-loss market, pulled in more than $175 Million in its first quarter on the market."[294]

292. To put it in perspective, data analytics and consulting company GlobalData "has put out a forecast that shows how GLP-1 RAs could rapidly redefine what big looks like in drug sales."[295] Indeed, with respect to Lilly, "[t]he analysts expect Mounjaro to bring in as much in 2029 as Lilly's entire portfolio did in 2023 . . . ."[296]

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survey finds, CNN (May 10, 2024) available at https://www.cnn.com/2024/05/10/health/ozempic-glp-1-survey-kff/index.html.

[293] *See* Obesity Care, Novo Nordisk Capital Markets Day, at Slide 8 (Mar. 7, 2024), available at https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/cmd/2024/P5-Obesity-Care.pdf.

[294] Taylor, Nick Paul, *Eli Lilly's edge over GLP-1 rivals tipped to drive Mounjaro sales to $34B by 2029*, Fierce Pharma (April 17, 2024), available at https://www.fiercepharma.com/marketing/eli-lillys-edge-over-glp-1-rivals-tipped-drive-mounjaro-sales-34b-2029 (last accessed Oct. 22, 2024).

[295] Taylor, Nick Paul, *Eli Lilly's edge over GLP-1 rivals tipped to drive Mounjaro sales to $34B by 2029*, Fierce Pharma (April 17, 2024), available at https://www.fiercepharma.com/marketing/eli-lillys-edge-over-glp-1-rivals-tipped-drive-mounjaro-sales-34b-2029.

[296] *Id.*

1. Defendants Spent Vast Sums of Money and Effort to "Medicalize" Obesity Treatment

293. In the public conscious today, many characterize obesity as a disease but when the AMA voted to take that stance in 2013, it was somewhat controversial and it was against the recommendation of its Committee on Science and Public Health.[297] The committee had been tasked with exploring the issue and had written a five-page opinion identifying several factors for why obesity should not be officially labeled as a disease which included the concern that it could "hurt patients, creating even more stigma around weight and pushing people into unnecessary—and ultimately useless—"treatments."[298]

294. Nonetheless, the AMA voted to characterize obesity as a disease "'due to its prevalence and seriousness.'"[299] Some argued that the real reason was driven more by a desire for doctors to drive up reimbursements for visits that involve obesity counseling.[300] The measure of obesity, typically BMI, provides subjective labeling of what qualifies as obese.[301] As a result, when a panel of experts "lower[ed] the BMI cutoff for overweight from 27 (28 in men) to 25", millions of additional people were labelled "overweight" and "obese" without any change in their weight, rendering them "eligible for treatment."[302]

295. To this day, ". . . whether obesity should be considered a disease has been referred

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[297] Brown, Harriet, *How Obesity Became a Disease: And, as a consequence, how weight loss became and industry*, The Atlantic (Mar. 24, 2014), available at https://www.theatlantic.com/health/archive/2015/03/how-obesity-became-a-disease/388300/

[298] *Id.*

[299] *Id.*

[300] *Id.*

[301] *Id.*

[302] *Id.*

to by health experts as 'one of the most polarizing topics in modern medicine.'"[303]

296. Recognizing obesity as a disease did not require that its treatment involve pharmaceutical intervention. Traditionally, obesity treatment involved lifestyle interventions including, but not limited to adopting a healthy diet, exercising, improving sleep, and addressing the underlying factors contributing to over-eating. When it discovered that GLP-1 RAs had potential as a weight-loss product, Novo began working to change the medical consensus as it relates to obesity treatment including advocating for pharmaceutical treatment for obesity and minimizing lifestyle interventions. In time, Lilly joined in that effort.

297. Defendants have spent millions of dollars marketing the belief that sustained weight loss is only achievable by using their medications, while minimizing the efficacy of the conventional, evidence-based lifestyle approaches to obesity.

298. For example, an unbranded Novo campaign "Share the Weight" features numerous DTC videos by Novo. One such exemplar video portrays an overweight woman consistently exercising and eating a healthy diet and saying "if it was only about effort we would have overcome obesity years ago" and that "getting healthy requires help from a doctor."[304]

299. A different Novo DTC campaign – "Truth about Weight" – features a series of videos showing overweight individuals eating health foods and exercising while showing their disappointment as they don't lose weight, and conveying messages such as "long term health goes beyond dieting" and "exercise alone may not be enough for you" before concluding with the

[303] Belluz, Julia, *Are We Thinking About Obesity All Wrong?*, New York Times (Guest Essay) (Sept. 19, 2024), available at https://www.nytimes.com/2024/09/19/opinion/obesity-disease-ozempic-weight-loss.html.

[304] https://www.youtube.com/watch?v=sPrhwdl-xE8 (accessed Nov. 7, 2024).

individuals visiting a doctor for help. [305]

300. Lilly also has similar DTC advertisements. The campaign "Living with Obesity" features a woman talking about how "we've been conditioned to say that people who live in larger bodies are lazy, eating too much. They don't exercise . . . It's just not true."[306] The woman proceeds to talk about how exercise hasn't worked because even if she lost weight, it would "always stop working,"[307] and discusses how the "experts" at the Obesity Action Coalition (an advocacy group funded by Novo and Lilly, as discussed below) say obesity is a disease that requires pharmaceutical treatment.

301. Lilly's Chief Customer Officer, Patrik Jonsson, acknowledged in 2022, that the over 100 million people suffering from obesity in the U.S. who were not being treated with pharmaceuticals were a "[v]ery huge opportunity in front of us" before continuing that there was a "lot of work required to ***medicalize obesity***."[308]

302. Mr. Jonsson also discussed other efforts being made to support pharmaceutical intervention as a treatment for obesity including conducting research that would show other health conditions that were improved by weight loss: "And we are currently doing five outcome studies that we believe will have a high relevance in order to ***change the treatment landscape*** in NASH and chronic kidney disease (inaudible) and one in morbidity and mortality outcomes study as well, and all those will have the opportunity to really ***medicalize be the obesity market***."[309]

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[305] https://youtu.be/7UYDWmaQmV4?si=7QAlsBrba4igXoCK (last accessed Nov. 7, 2024); https://www.youtube.com/watch?v=kcc4VFV_2gw&list=PL3xIWWD6Vj9oba3TRoYtNUoznFH6E83iL&index=2 (last accessed Nov. 7, 2024).

[306] https://www.youtube.com/watch?v=Vouu1caRu4M (accessed Nov. 7, 2024).

[307] *Id*.

[308] Eli Lilly & Co Conf Presentation Call 2022315.pdf (emphasis added).

[309] *Id*.

303. Defendants also needed to make sure that there was access to these drugs which meant that there would need to be insurance coverage. While at the UBS Global Healthcare Conference in May of 2022, Lilly's then-Executive Vice President and President of Diabetes and Obesity Mike Mason made clear that access in the obesity market would depend on the ability to get coverage: "the main driver in the evolution of the obesity market will be access. So you need to unlock [ph] Part D coverage, that's what the Treat and Reduce Obesity Act are trying to do. You also not only need to get access at the payers, but then employers got to opt into that coverage. So that's the most important thing to develop the obesity market."[310]

304. Lilly knew there were limits to what Medicare would cover for obesity so it tried to create enough data to show that the GLP-1 RAs could be used to treat other health conditions that were or would more likely be covered by Medicare. As Lilly's Chief Scientific Officer Dan Skovronsky explained during a Goldman Sachs Global Healthcare Conference on September 17, 2022: "in terms of monetizing the opportunity in the Medicare setting because it would seem the bar is high to expect Medicare to reimburse obesity, right? There are ***backdoors into increasing usage on the Medicare***, you're exploring sleep apnea, you're exploring NASH."[311]

305. The importance of Medicare and other insurance coverage was necessary to grow the obesity medication market and a key driver in the large monetary contributions and other efforts made to lobby and align with advocacy groups. Similarly, Novo recognized that they needed to lobby to expand Medicare coverage.[312] Novo's 2019 Capital Days presentation called

[310] Eli Lilly & Co Conf Presentation Call 2022524 DN000000002983664779.pdf.

[311] Eli Lilly at Citi's 17th Annual BioPharma Conference (Sep. 7, 2022), https://web.archive.org/web/20221001135415/https://investor.lilly.com/webcasts-and-presentations (emphasis added).

[312] https://www.novonordisk.com/content/dam/nncorp/global/en/investors/pdfs/capital-markets-day/Capital%20markets%20day%202019%20presentation.pdf

for "engaging with a broad range of coalition partners" to advocate for obesity care and Medicare coverage.[313]

306. Defendants also went directly to the people and targeted consumers with buzzy social media campaigns, emotional impact videos, and top-notch celebrity endorsements. When Americans turned on their TV or logged into their computer, they were met with the message that they needed drugs for weight loss and assured by the happy, smiling faces of everyone taking the drug. And thanks to the post-Covid advent of telehealth providers, a prescription was just a click away from the comfort of their couch.

307. In sum, Defendants took the public debate about "obesity as a disease" and expanded that to advocate for the best treatment for that disease being a pharmaceutical intervention because traditional treatments such as diet, exercise, and improved sleep where simply not enough for most people.

308. In their quest to maximize the size of the new obesity market, Defendants disregarded the boundaries set by FDA approvals and ignored basic truths about the weight loss associated with their drugs. Defendants routinely promoted Ozempic and Mounjaro as contributing to weight loss even though the drugs were not approved for that indication. They targeted marketing in various forums, including social media, to vulnerable groups who would be prone to weight loss messages regardless of their BMI or other health conditions. Defendants partnered with telemedicine companies to get widespread distribution of their drugs with as little supervision as possible. Defendants failed to disclose the risks of these drugs and failed to disclose that patients would likely have to be on these drugs for the rest of their lives to maintain the weight loss and that if they came off the drugs and gained some or all of the weight back, they would actually be

[313] *Id.*

less healthy than they were when they started.

2. Defendants Took a Multifaceted Approach and Spent Hundreds of Millions of Dollars to Change the Way Doctors Viewed Weight-Loss Drugs and Influence Prescriber Behavior

309. Defendants engaged in a multipronged approach to control and manipulate the universe of knowledge around GLP-1 RAs and obesity treatment including, but not limited to making direct payments to doctors, many of whom were influential in the relevant disciplines, so that they would promote the use of GLP-1 RAs; writing, promoting or funding articles regarding the safety and efficacy of the GLP-1 RAs; speaking at conferences regarding the safety and efficacy of GLP-1 RAs; participating in and influencing health care advocacy groups focused on obesity and obesity treatment; conducting continuing medical education seminars related to GLP-1 RAs; and spending millions of dollars lobbying for prescription drug coverage of GLP-1 RAs.

a. Direct Payments to Physicians

310. Not surprisingly, there is evidence that doctors prescribe more of a drug if they receive money from a pharmaceutical company linked to that drug.[314] Defendants made voluminous direct payments to physicians. This information is accessible through the federally mandated Open Payments database.

311. The Open Payments program is a national disclosure program that is intended to promote a more transparent and accountable health care system. It contains a publicly accessible database of payments that reporting entities, including drug and medical device companies, make to covered recipients such as physicians. There are generally three categories of payments that are

[314] Hannah Fresques, *Doctors Prescribe More of a Drug If They Receive Money from a Pharma Company Tied to It*, ProPublica (Dec. 20, 2019), https://www.propublica.org/article/doctors-prescribe-more-of-a-drug-if-they-receive-money-from-a-pharma-company-tied-to-it (including quotes from Novo Nordisk and Lilly).

reported: general payments, research payments, and ownership and investment interests.

312. According to Open Payments, between 2018 and 2023, Novo paid approximately $153 Million[315] in general payments (*e.g.*, marketing, consulting, travel, food and beverage, etc.) to doctors: $27.9 Million (2018); $26.8 Million (2019); $15.2 Million (2020); $27.3 Million (2021); $33.9 Million (2022); and $21.9 Million (2023). In 2022 alone, Novo purchased over 450,000 meals for doctors.[316]

313. Similarly, Lilly purchasing doctors 184,000 meals amounting to roughly $3.5 Million in 2022 while promoting its drugs Mounjaro and Trulicity.[317]

314. Over the past decade, a minimum of 57 physicians in the United States each accepted at least $100,000 from Novo in payments associated solely with Wegovy or Saxenda. A Reuters special report found these physicians were an influential group: Forty-one were obesity specialists who run weight-management clinics, work at academic hospitals, write obesity-treatment guidelines or hold top positions at medical societies.[318]

315. Critically, Reuters examined Novo's spending among experts involved in crafting five prominent sets of obesity-treatment guidelines for doctors. Among the 109 authors and reviewers credited in the guidelines, 53 had accepted cash or in-kind payments between 2013 and

[315] https://openpaymentsdata.cms.gov/company/100000000144.

[316] https://www.forbes.com/sites/johnlamattina/2023/07/20/fattening-doctors-to-promote-weight-loss-drugs/ (last accessed Oct. 10, 2024); https://www.statnews.com/2023/07/05/ozempic-rybelsus-novo-nordisk-meals-for-doctors (last accessed Oct. 10, 2024).

[317] https://www.forbes.com/sites/johnlamattina/2023/07/20/fattening-doctors-to-promote-weight-loss-drugs/ (last accessed Oct. 10, 2024).

[318] Terhune and Respaut, *Maker of Wegovy, Ozempic showers money on U.S. obesity doctors*, Reuters (Dec. 1, 2023) available at https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/.

2022 from companies that were selling or developing obesity drugs.[319]

316. Novo accounted for $8 Million of the $12.4 Million spent on these authors and reviewers, not including payments related to research, the Reuters analysis found.[320]

b. Key Opinion Leaders ("KOLs")

317. A key opinion leader ("KOL") is a trusted, well-respected professional with proven experience and expertise in a particular field. Often, in the pharmaceutical space, these thought leaders are physicians. These KOLs have extensive experience and carry significant influence which allows them to promote new drugs. Defendants have made paying and supporting KOLs a centerpiece of their influence strategy.

318. By way of example, Dr. Fatima Cody Stanford is an obesity specialist that frequently speaks on behalf of Novo, is featured on Novo's website, and has received payments directly from Novo.[321] Upon information and belief, Dr. Stanford is one of Novo's highest paid KOLs. Dr. Stanford also serves as an obesity consultant for Lilly.[322]

319. Dr. Stanford has spoken on the topic of Ozempic and Wegovy. One notable example occurred when she took part in an investigative piece conducted by the television news program "60 Minutes" where she promoted the safety and efficacy of GLP-1 RAs.[323] Dr. Stanford

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[319] *Id*.

[320] *Id*.

[321] https://openpaymentsdata.cms.gov/physician/807348 (last visited on Sept. 18, 2023). https://www.novonordisk-us.com/about/perspectives/changing-the-mindset-around-obesity.html (last visited on Sept. 18, 2023).

[322] Suran, Melissa, *As Ozempic's Popularity Soars, Here's What to Know About Semaglutide and Weight Loss*, JAMA (April 26, 2023) available at https://jamanetwork.com/journals/jama/article-abstract/2804462).

[323] https://www.youtube.com/watch?v=uaYLApCdKBo.

also states that obesity is a "brain disease" and that diet and exercise doesn't work."[324] Physicians Committee for Responsible Medicine later filed a complaint, alleging the 60 Minutes segment was an "unlawful weight loss drug ad" and that Dr. Stanford had not disclosed she had received significant payments from Novo.[325] Dr. Stanford also appeared on Oprah discussing obesity and promoting obesity drugs in September of 2023.[326] Her financial ties to Novo and Lilly were not fully disclosed during these appearances and not mentioned at all with respect to her appearance on Oprah.

320. Dr. Stanford also has sat on the advisory board of Calibrate, a telehealth provider for weight loss medications that has partnered with Novo; and she is included on Novo's website where she argues that access to Novo's weight-loss drugs is an issue of equity and disparity for communities of color.[327] Again, the full financial relationship between Dr. Stanford and Novo is not disclosed on Novo's website.

321. Similarly, Novo has used Dr. Lee Kaplan to advocate for the use of weight-loss medicines, including Wegovy. Dr. Kaplan is the Chief of Obesity Medicine at Dartmouth College's medical school; and previously was the head of the Obesity, Metabolism and Nutrition Institute at Massachusetts General Hospital and a teacher at Harvard Medical School. He is a powerful messenger for Novo and they paid him approximately $1.4 Million by between 2013 and 2022.[328]

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[324] *Id*.

[325] https://www.pcrm.org/news/news-releases/cbs-60-minutes-news-segment-was-unlawful-weight-loss-drug-ad-physicians.

[326] https://jamanetwork.com/journals/jama/article-abstract/2804462.

[327] https://www.novonordisk-us.com/about/perspectives/changing-the-mindset-around-obesity.html (last visited on Sept. 18, 2023).

[328] Terhune and Respaut, *Maker of Wegovy, Ozempic showers money on U.S. obesity doctors*

322. Lilly utilizes the same strategy. One of their KOLs is Dr. Marschall Runge, Executive Vice President for Medical Affairs and Chief Executive Officer of Michigan Medicine since March 2015 and Dean of the Medical School since January 2016.

323. Dr. Runge served on Ely Lilly's Board of Directors from 2013 until his recent retirement. During that time, on April 12, 2017, Dr. Runge published an article about obesity care without disclosing his financial relation to Lilly. Between 2021 and 2023, Lilly paid Dr. Runge a total of $926,147.

324. Lilly has also funded Dr. Ania Jastreboff since at least 2018. Dr. Jastreboff has appeared on Oprah discussing the benefits of GLP-1 RAs for the treatment of obesity.[329] Dr. Jastreboff has provided medical education through The Obesity Society, advocating for the use of pharmaceutical treatment for obesity.[330] Between 2020 and 2023, Lilly paid Dr. Jastreboff nearly $100,000.[331]

325. Dr. Ania Jastreboff was the first author on the The Obesity Society's 2018 position statement defining obesity as a disease and advocating for additional treatments where she disclosed that she received consulting fees from both Novo and Lilly.[332]

326. EveryBODY Covered is a campaign for obesity care coverage that is led by the Alliance for Women's Health & Prevention and funded by Lilly.[333] It features articles from KOLs

(Dec. 1, 2023), available at https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/.

[329] https://youtu.be/kMI9b3_TWt0?si=mmq6gSTu1W8igLun.

[330] https://www.obesity.org/meetings-education/grandrounds/.

[331] https://openpaymentsdata.cms.gov/company/100000000088.

[332] Obesity as a Disease: The Obesity Society 2018 Position Statement, available at https://www.obesity.org/wp-content/uploads/2019/04/Jastreboff_et_al-2019-Obesity.pdf.

[333] Everybodycovered.org and https://www.instagram.com/everybodycovered/.

such as Dr. Maria Abreu, who argue that "Obesity is Not a Lifestyle."[334] The article does not disclose that Dr. Abreu is a paid consultant for Lilly.[335]

c. Defendants Use Advocacy Groups to Influence Medical and Public Opinion Regarding Weight-Loss Drugs

327. Defendants directly or indirectly pay or influence numerous influential advocacy groups to influence medical and public opinion regarding obesity, the treatment for obesity, and the safety and efficacy of GLP-1 RAs. These include, among others, The Obesity Society, The Obesity Action Coalition, Obesity in Action Coalition, American Board of Obesity Medicine, and Stop Obesity Alliance.

328. The Obesity Society. The Obesity Society bills itself as "the leading professional society focused on obesity science, treatment and prevention" claiming to have over 2,800 members worldwide.

329. Former President of The Obesity Society, researcher Dr. Donna Ryan, was instrumental in persuading the U.S. Office of Personnel Management to cover Wegovy and similar drugs for millions of federal workers.[336] One analysis found that she has accepted more than $1 Million from Novo over the last decade, including $600,691 related to Wegovy and Saxenda.[337]

330. Current President of The Obesity Society, Dr. Jamy Ard of Wake Forest University, oversees the group's effort to write new "standards of care," which primary-care doctors often use

[334] https://news.med.miami.edu/dr-maria-abreu-obesity-is-not-a-lifestyle/ (linked from everybody Covered Instagram).

[335] https://www.practiceupdate.com/author/maria-abreu/4098.

[336] Terhune and Respaut, *Maker of Wegovy, Ozempic showers money on U.S. obesity doctors* (Dec. 1, 2023), available at https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/.

[337] *Id.*

as a quick-reference guide, with advice on Wegovy and similar therapies.[338] Dr. Ard has accepted more than $200,000 from Novo, according to Reuters.[339]

331. The Obesity Action Coalition. The Obesity Action Coalition ("OAC") claims to be "the nation's leading voice on obesity" with "more than 85,000" members.

332. Novo is "a long-time supporter" of OAC, and routinely renews their support of OAC's Chairman's Council at the Platinum level.[340]

333. In 2012, Robert Kushner served on the Board of Directors for the OAC.[341] That same year, ahead of the vote by the AMA to classify obesity as a disease, Dr. Kushner published "Clinical Assessment and Management of Adult Obesity" in the American Heart Association Circulation Journal arguing that obesity should be classified as a disease.[342] Dr. Kushner has previously disclosed that he received funding from Novo as a consultant for his research between 2008-2012.[343] Dr. Kushner has been a member of Novo's Medical Advisory Board from 2016 to the present.[344]

334. On March 21, 2013, Dr. Kushner published in the Obesity Journal on the 2013 Updated Obesity Guidelines; backed by American Association of Clinical Endocrinologists, The

[338] *Id*.

[339] *Id*.

[340] https://www.obesityaction.org/novo-nordisk-renews-support-for-oac-chairmans-council-at-platinum-level/.

[341] Kushner, Clinical assessment and management of adult obesity (2012 Dec 11), 126(24):2870-7. doi: 10.1161/CIRCULATIONAHA.111.075424. PMID: 23230316.

[342] *Id*.

[343] https://onlinelibrary.wiley.com/doi/epdf/10.1002/oby.20821.

[344] https://www.feinberg.northwestern.edu/faculty-profiles/az/profile.html?xid=11686.

Obesity Society, and American Society for Metabolic and Bariatric Surgery.[345] The Guidelines for the Management of Overweight and Obesity in Adults (2013) included an appendix of the committee members and their relationships with industry, including Novo. Prior to the committee issuing guidelines that obesity should be treated as a disease, both committee co-chairs had received funding from Novo – and five additional committee members had received funding from Novo.[346] Two of the committee members also received funding from Lilly.[347]

335. Novo has referred to its partnership with the OAC and credited it with "making a big difference" in giving a voice to those living with obesity.[348]

336. Both Novo and Lilly contribute more than $100,000 to the OAC annually.[349]

337. American Board of Obesity Medicine. The American Board of Obesity Medicine is a professional credentialing organization for the practice of Obesity Medicine. One of its stated goals is "to improve access to high-quality clinical services for patients with obesity by increasing the number of competent physicians that can treat this complex, chronic disease."

338. The former Director of the American Board of Obesity Medicine who served from 2017 to November of 2021 received payments from Novo during her time as director of the

[345] Mechanick, *et al*., *Clinical practice guidelines for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient--2013 update*, American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery, 2013 Mar;21 Suppl 1(0 1):S1-27. doi: 10.1002/oby.20461. PMID: 23529939; PMCID: PMC4142593.

[346] https://onlinelibrary.wiley.com/doi/epdf/10.1002/oby.20821.

[347] *Id*.

[348] https://www.novonordisk.com/content/dam/Denmark/HQ/Commons/documents/Novo-Nordisk-Annual-Report-2015.PDF, at 28.

[349] https://www.obesityaction.org/corporate-partners/ (last accessed Sept. 18, 2023).

American Board of Obesity Medicine.[350] She has also promoted the GLP-1 RAs for weight loss as part of a telehealth company and continues to receive payments.[351]

339. According to Open Payments Data, at least one member of the American Board of Obesity Medicine that helped write the guidelines for obesity management received payments directly from Novo during the same time he wrote those guidelines.[352]

340. The American Board of Obesity Medicine lists public health "partners" on their website.[353] Novo serves on the board and/or provides direct financial contributions to many of these public health advocacy groups: (1) OAC (discussed above); (2) American Society for Metabolic and Bariatric Surgery;[354] and (3) Stop Obesity Alliance.[355]

341. Stop Obesity Alliance operates out of George Washington's Milken Institute School of Public Health and advocates for insurance coverage and expanded pharmaceutical obesity treatment. Both Lilly and Novo are corporate sponsors of Stop Obesity Alliance.

342. All About Obesity is yet another advocacy group pushing for treatment services for those living with obesity.[356] Both board members receive funding for grants, consulting, or speaking from Lilly and Novo.[357] Novo went on and partly funded the creation of the website in

[350] https://joinfound.com/pages/medication-biology (last visited on Sept. 18, 2023); https://openpaymentsdata.cms.gov/physician/1294300 (last visited on Sept. 18, 2023); https://www.linkedin.com/in/rekha-kumar-m-d-m-s-70b481237/ (last visited on Sept. 18, 2023).

[351] *Id*.

[352]https://openpaymentsdata.cms.gov/physician/1379381 (last visited Sept. 18, 2023); see also https://www.abom.org/karl-nadolsky/.

[353] https://www.abom.org/ (last visited on Sept. 18, 2023).

[354] https://asmbs.org/corporate-council (last visited Sept. 18, 2023).

[355] https://stop.publichealth.gwu.edu/membership (last visited on Sept. 18, 2023).

[356] https://allaboutobesity.org/about-us/.

[357] https://allaboutobesity.org/declaration-of-interests/.

2021.

343. Lilly also sponsors The World Obesity Federation which is another advocacy group that runs the campaigns "Let's Talk About Obesity & ___" as well as World Obesity Day.[358] This campaign is unique in that it also advocates for increased treatment for youth and kids.

344. Novo and Lilly both:

- are Corporate Partners/Gold Sponsors for American Association of Clinical Endocrinologists;[359]
- serve on Endocrine Society "Corporate Liaison Board";[360]
- are members of American College of Cardiology ("ACC") "Industry Advisory Forum," in which they contribute at least $25,000 annually (the ACC website says the Industry Advisory Forum "organization[s] will have a front-row seat to discussions on topics of mutual interest and importance impacting the cardiovascular healthcare environment.");
- sit on the "Chairman's Council" for the OAC, and have been for several years;[361] and
- provided financial backing to the OAC "Your Weight Matters" campaign[362] where, as part of the campaign, a new public service announcement ("PSA") was launched to encourage Americans to "take control of their health" by starting "vital" conversations with their healthcare providers (those who took part in the campaign, *i.e.*, took the challenge, received a book that included information on "medical weight management" and the "FDA-approved prescription medications, including injections and oral medications, designed to assist with chronic weight management").

[358] https://www.worldobesityday.org/.

[359] https://pro.aace.com/about/corporate-aace-partnership-cap (last accessed Oct. 17, 2024).

[360] https://www.endocrine.org/partnerships (last accessed July 8, 2024).

[361] *See* https://www.obesityaction.org/wp-content/uploads/OAC-Annual-Report-2023.pdf (last accessed Oct. 9, 2024).

[362] *See* https://www.fiercepharma.com/marketing/eli-lilly-novo-nordisk-and-other-big-pharmas-back-oacs-your-weight-matters-campaign (last accessed Oct. 9, 2024).

d. Defendants Exert Influence over Continuing Medical Education Regarding Obesity and GLP-1 RAs

345. Defendants recognized that there was a historical reluctance among prescribers to prescribe weight loss medication – particularly if the resulting weight loss was a modest 5 to 7%.[363] In 2015, Novo admitted that "many people – including some doctors and healthcare professionals – simply don't accept that obesity is a disease. Until we can convince them otherwise, we'll struggle" to maximize sales.[364] Novo concluded that their 10-year plan to establish a leading position within treatment for obesity "starts by educating doctors."[365]

346. Defendants operate comprehensive, integrated education for health care providers as part of their online websites where the messaging consistently reinforces that obesity is a disease and advocates for pharmaceutical interventions.

347. Novo offers robust continuing medical education through its website "Rethinking Obesity." One of the first training modules available is one entitled "Virtual Obesity Clinics Programme" with the promise that physicians will learn "how to introduce virtual patient consultations and best practices into an existing obesity clinic model."[366]

348. Lilly offers its own continuing medical education online portal that contains disease resources, trainings, CME, and lectures by KOLs.[367]

349. In addition to the educational materials available directly from Defendants, they

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[363] Eli Lilly at the UBS Virtual Global Healthcare Conference (May 19, 2020), https://web.archive.org/web/20201204114841/https://investor.lilly.com/webcasts-and-presentations.

[364] https://www.novonordisk.com/content/dam/Denmark/HQ/Commons/documents/Novo-Nordisk-Annual-Report-2015.PDF, at 28.

[365] *Id*.

[366] https://www.rethinkobesity.global/global/en/resources/ecme-and-medical-education.html.

[367] https://medical.lilly.com/us/diseases/patient-education-resources/obesity/obesity.

have also funded education through various associations. By way of example, Novo provides "independent" educational grants to Medscape, which provides free electronic CME on obesity and weight management to U.S. physicians.[368] These modules include education that encourages drugs for weight loss.[369] Lilly has funded continuing medical education such as a session on "Redefining Obesity Management" at the 12th Annual Obesity Forum.[370]

350. Defendants also present at industry and academic conferences on the topic of obesity. Recently, Novo also held an "unbranded" symposium discussing the need for increased care and insurance coverage in obesity.[371] Both Lilly and Novo are sponsors of the "Obesity Care Week" Conference in the United States[372] that advocates for "clinically-based care" for obesity, which primarily means use of GLP-1 RAs.

351. Lilly has presented on the topic of Obesity at the American Diabetes Association,[373] Obesity Week, the European Association for the Study of Diabetes, American Heart Association, Endocrine Society, and European Association for the Study of Obesity/European Congress on Obesity.[374] Specific presentations include the "Development of the Pediatric Weight Questionnaire" and "Real-World Characteristics of Adults with Obesity or Overweight Treated with Tirzepatide in the US."[375] The Obesity Week presentation poster acknowledged that some

[368] https://www.rethinkobesity.global/global/en/resources/ecme-and-medical-education.html.

[369] https://www.medscape.org/viewarticle/1000779.

[370] https://events.vindicocme.com/en/15kYU86/g/xM5BD6TC2R/12th-annual-obesity-forum-redefining-obesity-management-4a2BUmoci1/overview.

[371] https://www.ispor.org/docs/default-source/intl2023/novo-nordisk-presentation.pdf?sfvrsn=3179cf91_0.

[372] https://www.obesitycareweek.org/partners/.

[373] https://medical.lilly.com/us/science/conferences/obesity/ada2024.

[374] https://medical.lilly.com/us/science/conferences/obesity.

[375] https://medical.lilly.com/us/science/conferences/obesity/ow2024.

patients are initiating tirzepatide when they are a normal body weight at baseline – that is, the poster recognizes there is off-label usage of the drug.[376]

e. Defendants Influence the Relevant Literature

352. Defendants are involved directly or indirectly in significant amounts of literature intended to influence doctors' perceptions of obesity, treatment for obesity and the safety and efficacy of GLP-1 RAs.

353. For example, one analysis showed that Novo shifted public perception of obesity "thanks to the effective messaging of the company's spokespeople, who, according to our analysis of 3,263 English-language articles published in the last two years, became the most influential spokespeople in the whole obesity debate. . . ."[377]

354. Novo has been investing in relevant literature dating back to 2013:

- On April 1, 2013, Holly R. Wyatt published an "update on Treatment Strategies for Obesity" in the Endocrine Society Journal and disclosed financial grant money from Novo.[378]
- On October 24, 2017, University of Leeds researchers called semaglutide "anti-obesity drug" after Novo funded their research on appetite control.[379]
- In 2021, Novo funded research regarding the genetics of obesity.[380] This is

[376]https://assets.ctfassets.net/mpejy6umgthp/13JiVNYXvN7llHOHNRza8j/4c08788f73c6e6caa78a48d6a6c1ea5a/VV-TZPPT1_OW2024_KAN_REAL_WORLD_CHARACTERISTICS_DV-022561_V2.2.pdf.

[377] Koleva, Maya, *Novo Nordisk changed the obesity debate. But its reputation is on the line*, Cometric (Mar. 13, 2024) available at https://commetric.com/2024/03/13/novo-nordisk-changed-the-obesity-debate-but-its-reputation-is-on-the-line/.

[378] Wyatt, Holly R., *Update on Treatment Strategies for Obesity*, The Journal of Clinical Endocrinology & Metabolism, Volume 98, Issue 4, 1 April 2013, Pages 1299–1306, available at https://doi.org/10.1210/jc.2012-3115.

[379] Univ. of Leeds, *Anti-obesity drug acts on brain's appetite control system* (Oct. 24, 2017), available at https://www.leeds.ac.uk/news-health/news/article/4122/anti-obesity-drug-acts-on-brain-s-appetite-control-system.

[380] https://www.nature.com/articles/s41576-021-00414-z#author-information.

consistent with Novo's approach to market the primary cause of obesity as genetics that requires pharmaceutical treatment.

- Novo has also funded research regarding the pervasiveness, impact, and implications of weight stigma.[381]

- In 2022, Novo published the results of its ACTION IO study focused on increasing treatment of teenagers with obesity, including the use of weight loss drugs. ACTION stands for Awareness, Care & Treatment in obesity Management – International Observation Among Teenagers.[382]

- The 2023 Cardiovascular outcomes of the SELECT Trial – which was the basis for FDA approval of a label change for cardiovascular benefits – was conducted by Novo and an "academic steering committee."[383] This academic steering committee had received over $7.5 Million dollars in payments from Novo between 2015-2022.[384]

355. Similarly, Lilly has been funding similar research dating back to 2010:

- Dating back as early as 2010, Lilly funded research that resulted in publications titled "Nonsurgical Weight Loss for Extreme Obesity in Primary Care Settings."[385]

- Lilly's clinical trials program includes almost 17,000 individuals being studied for just tirzepatide.[386]

- Lilly has also done significant research into the attitudes of patients, physicians, and employers regarding obesity in an attempt to increase the sales of their drugs.[387]

356. Novo and Lilly were both involved in funding other research:

- In May of 2013, American Association of Clinical Endocrinologists releases

[381] https://pmc.ncbi.nlm.nih.gov/articles/PMC9046114/.

[382] https://www.rethinkobesity.global/content/rthkobesity/global/en/resources/obesity-resources-for-physicians-and-patients.html#section18.

[383] https://weightandhealthcare.substack.com/p/the-semaglutide-wegovy-cardiovascular

[384] *Id*.

[385] https://pubmed.ncbi.nlm.nih.gov/20101009/.

[386] https://www.biospace.com/business/lillys-sprawling-obesity-clinical-program-underscores-challenges-for-biotechs.

[387] https://medical.lilly.com/us/diseases/disease-education-resources/obesity/obesity/education-resources/observe-study-overview.

Consensus Statement on "Comprehensive Diabetes Management Algorithm" that mentions obesity fifty (50) times; 12 of 19 authors had ties to Novo or Lilly.[388]

- In May of 2013, Novo and Lilly, among others, provided grants to a working group's that are publishing with the American Diabetes Association and Endocrine Society.[389] Under the Participants Section, the Abstract says: "The workgroup meeting was supported by educational grants to the American Diabetes Association from Lilly USA, LLC and Novo and sponsorship to the American Diabetes Association from Sanofi. The sponsors had no input into the development of or content of the report."

- Lilly and Novo both paid personal fees to the author of the study "Influence and effects of weight stigmatization in the media."[390] Novo has separately funded the Joint International Consensus Statement for ending the Stigma of Obesity, and Lilly had paid speaker fees to one of the authors.[391] This research concluded that the prevailing view is that "obesity is a choice and that it can be entirely reversed by voluntary decisions to eat less and exercise more" and that this view can "exert negative influences" on access to treatments and research.[392]

- Lilly and Novo continue to partner together on obesity research and expanding obesity treatments.[393] To date these treatments have made Novo nearly $50 Billion in sales of Ozempic and Wegovy since 2018.[394] Mounjaro and Zepbound now account for approximately 40% of Lilly's total sales, which exceed billions of dollars.[395]

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[388] https://diabetesed.net/page/_files/AACE-2013-DM-consensus-statement.pdf (last accessed July 14, 2024).

[389] Seaquist, *et al*., *Hypoglycemia and diabetes: a report of a workgroup of the American Diabetes Association and the Endocrine Society*, J. Clin. Endocrinol Metab. (2013 May), 98(5):1845-59. doi: 10.1210/jc.2012-4127. Epub 2013 Apr 15. PMID: 23589524.

[390] https://pmc.ncbi.nlm.nih.gov/articles/PMC9125650/.

[391] https://www.nature.com/articles/s41591-020-0803-x.

[392] https://www.nature.com/articles/s41591-020-0803-x#Sec1.

[393] https://www.imisophia.eu/partners.

[394] https://www.usatoday.com/story/news/health/2024/09/24/senate-hearing-novo-nordisk-ceo-ozempic-wegovy-prices/75348020007/.

[395] https://www.barrons.com/articles/eli-lilly-stock-weight-loss-drugs-market-cap-681cf0f7.

f. Defendants Pay Lobbying Groups to Support Legislation Authorizing Reimbursements for GLP-1 RAs

357. Medicalizing obesity treatment would do little for Defendants profits if there was no access to GLP-1 RAs. Such access includes the ability to pay for these very expensive drugs – Wegovy (approx. $1,350/mo.), Mounjaro (approx. $1,023/mo.), and Zepbound (approx. $1,060/mo.).

358. Key to making the GLP-1's more affordable was getting them covered by Medicare. Not only would Medicare coverage make obesity drugs affordable for many people who currently find them out of reach, it would likely push private insurers to likewise cover these drugs.[396] As Lilly's Mike Mason previously noted, the key to expanding the market for obesity drugs was "unlock[ing]" coverage under Medicare Part D.[397]

359. Unfortunately for Defendants, drugs used for weight loss were excluded by Congress when it established Medicare's Part D prescription drug benefit in 2003. This ban effectively deprives drugmakers of millions of potential customers.[398]

360. So, Defendants spend millions of dollars per year trying to lobby for changes in the law. A primary focus of that lobbying is the proposed Treat and Reduce Obesity Act, which has been introduced in Congressional sessions annually since 2012. The Treat and Reduce Obesity Act would require Medicare to cover, among other treatments, chronic-weight-management

[396] https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicares-favor (last visited Oct. 23, 2024).

[397] Eli Lilly at UBS Global Healthcare Conference (May 24, 2022), https://web.archive.org/web/20220603141033/https://investor.lilly.com/webcasts-and-presentations.

[398] https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicares-favor (last visited Oct. 23, 2024).

drugs.[399]

361. From 2012 to 2023, Novo spent over $35 Million on lobbying for obesity drug coverage: $2.24 Million (2012); $2.06 Million (2013); $2.40 Million (2014); $2.61 Million (2015); $2.51 Million (2016); $1.91 Million (2017); $4.01 Million (2018); $2.78 Million (2019); $4.63 Million (2020); $3.21 Million (2021); $4.6 3 Million (2022); and $4.07 Million (2023).[400]

362. In 2021, Novo also gave significant sums, in the hundreds of thousands, to the Congressional Black Caucus Foundation for Medicare coverage support, and has also contributed to the Congressional Hispanic Caucus and Congressional Asian Pacific American Caucus.[401] The Congressional Black Caucus, Congressional Hispanic Caucus and Congressional Asian Pacific American Caucus have all backed a bill on health disparities that was revised in 2022 to remove Medicare's prohibition on covering prescriptions for weight loss similar to The Treat and Reduce Obesity Act.[402]

363. While Lilly's efforts to influence such legislation came later, it benefitted from the groundwork laid by Novo and also sought to advance the effort to get passage of the The Treat and Reduce Obesity Act.[403]

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[399] https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin (last visited Sept. 17, 2023); *see also* https://www.fiercepharma.com/pharma/novo-nordisk-eli-lilly-and-boehringer-get-behind-lawmakers-bill-enable-obesity-drug-coverage (last visited Sept. 17, 2023)

[400] *See, e.g.*, OPEN SECRETS, *Novo Nordisk*, https://www.opensecrets.org/orgs/novo-nordisk/lobbying.

[401] *See* Pradhan, *Ozempic and Wegovy maker courts prominent Black leaders to get Medicare's favor*, NPR (Aug. 7, 2023), available at https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicares-favor.

[402] *Id*.

[403] *See, e.g.*, https://www.lilly.com/disease-areas/obesity ("We also join the obesity advocacy community—including medical, patient and health equity groups—to support the Treat and

364. From 2021 to August of 2024, Lilly spent over $2 Million lobbying for obesity drug coverage:[404] $390,000 (2021); $400,000 (2022); $900,000 (2023); and $320,000 (2024).[405] As reported by the *Associated Press* in December of 2023, "Lilly spent roughly $2.4 million lobbying since 2021" on obesity drug coverage issues, including lobbying related to the Treat & Reduce Obesity Act.[406]

365. The lobbying activities and contributions referenced above do not include the money that Defendants spend lobbying for inclusion of weight-loss drugs in prescription drug coverage through advocacy groups, such as the Obesity Care Advocacy Network,[407] and direct contributions to political campaigns for members for Congress.[408]

366. Morgan Stanley anticipates passage of The Treat and Reduce Obesity Act within the next few years and forecasts that U.S. revenue from weight-loss drugs will increase four-hundredfold by the end of the decade. Obesity looks "set to become the next blockbuster pharma category," it declared in a report last year, which also predicted that social media and word of mouth will create an "exponential virtuous cycle" around the new medications: a quarter of people with obesity will seek treatment from physicians, up from the current seven per cent, and more

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Reduce Obesity Act. The act is a step in the right direction to help modernize Medicare Part D to treat obesity as a chronic disease with evidence-based practices.").

[404] OPEN SECRETS, *Eli Lilly & Co*, https://www.opensecrets.org/orgs/eli-lilly-co/lobbying.

[405] *Id*.

[406] Amanda Seitz, *New weight loss drugs are out of reach for millions of older Americans because Medicare won't pay*, ASSOC. PRESS (Dec. 28, 2023), https://apnews.com/article/wegovy-ozempic-zepbound-medicare-obesity-weight-loss-02d4500e737d30d070d70907521a4fe0.

[407]https://assets.obesitycareadvocacynetwork.com/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0.pdf (last visited on Sept. 18, 2023).

[408] https://www.fiercepharma.com/marketing/health-group-lambasts-novo-nordisk-60-minutes-paid-news-program-weight-loss-med-wegovy (last visited Sept. 18, 2023).

than half of those who do will begin taking medicine.[409]

367. *Yahoo! Finance* reported that Novo and Lilly are trying to pursue a second avenue to gain Medicare coverage of GLP-1 RAs, by relying on other benefits from the drugs that might warrant reimbursement. For instance, Wegovy recently added a cardiovascular benefit and Lilly applied to expand Zepbound for sleep apnea.[410] These would be the "backdoors" referred to by Lilly's Dan Skovronsky regarding increasing usage on Medicare.[411]

368. There have also been efforts to push for employer-sponsored health plans to cover obesity medications. For example, Novo has published content on the Pittsburgh Business Group on Health's website regarding the need for obesity care.[412] This group advocates for employer's ability to provide healthcare coverage.

369. The push for Medicare coverage for GLP-1 RAs and making pharmaceuticals a primary treatment for weight loss is not without consequences. While Medicare coverage for weight-loss drugs may be a boom to Defendants, it has significant public policy ramifications. Researchers at Vanderbilt University and the University of Chicago found that, even with modest uptake of the medications, annual Medicare Part D expenses could cost the program between $13.6 to $26.8 Billion even if only 10% of people with obesity use them. It is likely that premiums would need to increase and other changes in priorities would need to occur. Authors of the study

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[409] https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin (last visited on Sept. 18, 2023).

[410] Anjalee Khemlani, *How Lilly is joining Novo in the crusade to circumvent Medicare's block on weight loss drugs*, YAHOO! FINANCE (June 24, 2024), https://finance.yahoo.com/news/how-lilly-is-joining-novo-in-the-crusade-to-circumvent-medicares-block-on-weight-loss-drugs-180112580.html.

[411] Eli Lilly at Citi's 17th Annual BioPharma Conference (Sep. 7, 2022), https://web.archive.org/web/20221001135415/https://investor.lilly.com/webcasts-and-presentations.

[412] https://pbghpa.org/why-people-struggle-to-maintain-weight-loss/.

questioned the economics of including semaglutide in Medicare Part D because it is not cost-effective compared to other methods of treating obesity (*e.g.*, lifestyle interventions) and "cannot be the only way – or even the main way – we address obesity as a society."[413]

3. Defendants Extensive Advertising Has Changed Prescriber Behavior While Driving Up Demand by Engraining Their Drugs in the Popular Culture

a. Defendants Have Collectively Spent Over a Billion Dollars on Branded Direct-to-Consumer and Unbranded Advertising

370. Once Novo recognized the significant potential of Ozempic, it took an aggressive marketing approach to make its GLP-1 RAs a household name.

371. Novo's marketing for Ozempic was so pervasive that, on July 10, 2023, the leading publication for the marketing and media industry, Advertising Age, declared Ozempic as "2023's buzziest drug" and one of the "Hottest Brands, disrupting U.S. culture and industry."[414]

372. The advertising blitz began on July 30, 2018 when Novo launched its first Ozempic television advertisement – "Magic" – that that repeated the catchy phrase "Oh, oh, oh, Ozempic!" set to the tune of the 1970s song "Magic." The catchy jingle helped Ozempic become widely recognized. The ad also noted that "you may lose weight" and that "adults lost on average up to 12 pounds" even though Ozempic is not approved for weight loss.[415]

373. From that time through 2023, Novo spent approximately $884 Million on television advertising in the United States to promote Ozempic and later, its other semaglutide, Wegovy (and

[413] https://www.vumc.org/health-policy/medicare-antiobesity-medications-nejm.

[414] https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-2023/2500571 (last visited on Sept. 17, 2023); *see also* https://www.mmm-online.com/home/channel/spending-on-ozempic-wegovy-surges/.

[415] *See* https://www.ispot.tv/ad/d6Xz/ozempic-oh.

another of its lesser known GLP-1 agonists, Rybelsus).[416]

374. One report indicated that Novo spent approximately $100 Million in advertising Ozempic in 2022 alone.[417] That year, Ozempic ranked as the sixth most advertised prescription drug brand with a U.S. measured media spend of $181 million, according to Vivvix spending data and Pathmatics paid social data.[418]

375. This massive spending resulted in cultural saturation and caused Ozempic to become a household name and engrained in pop culture. In 2022, Novo's "earned media coverage" (coverage they did not pay for) went "off the charts." In fall of that year, "Variety labeled Ozempic as 'Hollywood's Secret New Weight Loss Drug.'" Notably, in response to the press about Ozempic being used for weight loss, Novo stepped up its TV promotion of the drug even though it is not approved for weight-loss.[419]

376. Ozempic's place in the culture was unquestionable. Jimmy Kimmel joked about Ozempic at the Oscars;[420] Howard Stern joked about and discussed Ozempic (interestingly, Stern noted that the "catchy" theme song "distracts" the listener from actually hearing any of the listed side effects);[421] celebrities such as Queen Latifah became spokespersons; and other celebrities,

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[416] *See* Ritzau, *Novo Nordisk runs TV ads in US for multimillion-dollar sum*, MedWatch (Apr. 26, 2023), https://medwatch.com/News/Pharma___Biotech/article15680727.ece.

[417] https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin (last accessed Sept. 17, 2023).

[418] https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-2023/2500571?utm_source=exchange&utm_medium=email&utm_campaign=t5687390.

[419] Adams, Ben, *The top 10 pharma drug ad spenders for 2022*, Fierce Pharma (May 1, 2023), available at https://www.fiercepharma.com/special-reports/top-10-pharma-drug-brand-ad-spenders-2022.

[420] https://www.usatoday.com/story/life/health-wellness/2023/03/13/ozempic-sweeping-hollywood-celebrities-weight-loss/11428801002/ (last accessed Sept. 17, 2023).

[421] https://www.youtube.com/watch?v=QD-nCQn1Ads (last visited on Sept. 17, 2023).

such as Elon Musk and Chelsea Handler, admitted to using the drug, again for weight loss.[422]

377. All of this extensive marketing made demand for Ozempic and other GLP-1 RAs skyrocket. People wanted to use these drugs to lose weight, regardless of whether the drugs had been approved for that purpose or not. In some instances, it led to patients seeking prescriptions for GLP-1 RAs from their doctor rather than their doctor suggesting it as a treatment for obesity.

378. Lilly was able to benefit from the extensive marketing being conducted by Novo and the demand for GLP-1 RAs that the marketing created. But, in addition to piggybacking off of Novo's efforts, Lilly engaged in its own aggressive marketing campaign intending to establish itself as a legitimate rival in the market.

379. In 2023, Lilly spent $139 Million promoting Mounjaro – 16 times more than in 2022.[423] This was part of over $1 Billion spent marketing diabetes and weight loss drugs in 2023.

380. Lilly, which had been advertising its diabetes medication Trulicity since 2015, began marketing it with an eye toward weight loss in 2018 (it was not approved for weight loss). In its 2018 Trulicity advertising campaign "Do More," an overweight firefighter exclaims, "[Trulicity] comes in an easy-to-use pen, and I may even lose a little weight!"[424] This weight loss messaging continues in a series of advertisements in 2021 and 2022 called "On His Game," "Father-Son," and "My Sister" where the voiceover indicates that taking Trulicity can help you "lose up to 10lbs."[425] These advertisements were even targeted to Spanish speaking populations,

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[422] https://www.insider.com/ozempic-celebrities-denied-semaglutide-wegovy-weight-loss-drugs-khloe-kardashian-2023-3#chelsea-handler-said-she-was-on-semaglutide-without-realizing-it-7 (last accessed on Sept. 18, 2023).

[423] https://www.cnbc.com/2024/04/03/weight-loss-diabetes-drug-ad-spending-tops-1-billion.html

[424] https://www.ispot.tv/ad/dBhL/trulicity-do-more-firefighter.

[425] https://www.ispot.tv/ad/Oqgb/trulicity-on-his-game https://www.ispot.tv/ad/q4Kl/trulicity-father-son; https://www.ispot.tv/ad/bffc/trulicity-my-sister.

proclaiming "puedes perder hasta 10 LBS" in an advertisement from 2022.[426]

381. On February 13, 2020, Lilly partnered with Team USA and NBC for the Olympics.[427] In addition to partnering specifically with Team USA, Lilly also engaged many Team USA athletes as "brand ambassadors" on marketing health-related issues like diabetes. A Lilly spokesperson said the goal of the marketing campaign was clear: "to connect with Americans that may benefit from our medicines" and adding that "as a global healthcare leader, we can think of no better example of health and wellness than these elite athletes."[428]

382. In July of 2023, Lilly extended its marketing deal with Team USA and NBC, securing this partnership through the 2028 Olympic Games and Paralympic Games, both of which will be held in Los Angeles.[429] In that same month, Lilly released a television commercial for Mounjaro featuring Simone Biles, one of the most recognizable members of Team USA. The advertisement featured Simone Biles engaging with fans and then saying "you can do diabetes differently, with Mounjaro."[430]

383. In the run up to the 2024 Olympics in Paris, Simone Biles posted to her Instagram account a Mounjaro commercial in which she starred with her mom. The advertisement noted that she is not a diabetic and that her mom, Nellie, who is a type 2 diabetic, is not taking Mounjaro.

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[426] https://www.ispot.tv/ad/bKNt/trulicity-reduce-el-azcar-spanish.

[427] *See* https://corporate.comcast.com/press/releases/us-olympic-paralympic-committee-nbcuniversal-eli-lilly-and-company (last accessed October 9, 2024).

[428] *Id.*

[429] Nick Paul Taylor, *Lilly inks expanded Olympics deal, positioning it to push diabetes, cancer messaging through 2028*, Fierce Pharma (Jul. 12, 2023), https://www.fiercepharma.com/marketing/lilly-inks-expanded-olympics-deal-positioning-it-push-diabetes-cancer-messaging-through.

[430] *See* https://www.fiercepharma.com/marketing/eli-lilly-vaults-simone-biles-head-mounjaro-ad-campaign-partnering-olympian-tv-spot (last accessed Oct. 9, 2024).

The ad further says in a voiceover that "people taking Mounjaro lost up to 25 pounds" while noting in text that it is not approved for weight loss. In her comments, Simone Biles states: "It's always so exciting to get to work with my mom, especially on something so personal to us."[431]

384. On February 12, 2023, Lilly's first TV advertisement for Mounjaro—titled "What If"—aired during the Super Bowl. Lilly spent $19.6 Million on the advertisement. The commercial featured patients pondering the possibility of managing their type 2 diabetes "differently" and included statements that Mounjaro "helps your body regulate blood sugar and can help decrease the amount of food you eat,"[432] and that "people taking Mounjaro lost up to 25 lbs."[433] On a list for pharmaceutical advertising spending for the month, Lilly's "What If" ad ranked 4th.[434]

385. The net effect of these advertisements was to heighten interest in a medicated solution to weigh-loss, balloon the market for GLP-1 RAs, encourage off-label use for Ozempic and Mounjaro, and to target users of other diabetes medications to switch to GLP-1 RAs even though they never would have switched absent this unprecedented marketing. This expansion of the GLP-1 RA market came without concern for the safety and efficacy of these drugs.

b. Defendants' Use of Various Online or Digital Platforms

386. Defendants have created numerous marketing campaigns and online platforms designed to promote recognition of obesity as a disease and advocate for pharmaceutical treatment of obesity.[435]

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[431] https://www.instagram.com/simonebiles/?hl=en (last accessed Oct. 9, 2024).

[432] https://xtalks.com/eli-lilly-spends-big-on-first-mounjaro-tv-commercial-for-diabetes-3424/.

[433] https://www.ispot.tv/ad/1VpJ/mounjaro-what-if; https://www.pharmexec.com/view/eli-lilly-invests-heavily-in-debut-mounjaro-tv-ad-campaign-for-diabetes (discussing $19.6 million expenditure).

[434] https://xtalks.com/eli-lilly-spends-big-on-first-mounjaro-tv-commercial-for-diabetes-3424/.

[435] https://www.novonordisk.com/content/dam/nncorp/global/en/about-us/pdfs/corporate-

387. Novo created the It's Bigger than Me, Rethinking Obesity, and Truth About Weight campaigns. All of these Novo marketing campaigns featured DTC websites that gave consumers the opportunity to sign-up for email and other marketing materials.

388. Through these websites, Novo collected extensive data through quizzes and questionnaires taken by potential customers who were seeking information on weight loss. Upon information and belief, this data was funneled – as part of their omnichannel strategy – back into Novo's market strategy so that Novo could better target its marketing campaigns.

389. Novo also owns and operates several marketing campaign websites, such as "The Truth about Weight,"[436] that were purportedly created to educate on the science of obesity and create change in how obesity is understood and treated. It also created the advertising campaign website "It's Bigger Than Me"[437] that promotes the message that obesity is a chronic health condition that requires pharmaceutical drugs to manage.[438]

390. The "The Truth about Weight" website is also specifically intended to target minority communities, some of which have heightened rates of obesity. It has included the tag line "my weight, my culture" intended to convey the message that struggles to achieve weight loss through more traditional methods such as lifestyle interventions (*e.g.*, diet and exercise) will not work in light of cultural hurdles. The goal is to move this community toward believing that pharmaceutical interventions are the only answer. The website also suggests pushing back against doctors because they just might not get it, stating: "Many health care professionals know there's a science behind weight loss, but they may not know the impact that culture has on weight loss

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governance/annual-general-meetings/agm2019/uk/annual-report-2018.pdf, at 28

[436] https://www.truthaboutweight.com/ (last visited on Sept. 18, 2023).

[437] https://www.itsbiggerthan.com (last accessed Sept. 18, 2023).

[438] https://www.itsbiggerthan.com (last accessed Sept. 18, 2023)

needs." There are also "my weight, my culture" hashtags appearing on Instagram with an apparent focus to target Black, Brown, and Hispanic individuals.[439]

391. Lilly likewise was involved in various unbranded online platforms. For example, on October 18, 2024, Lilly announced that it was partnering with the OAC to launch[440] a "bias-free obesity image gallery" as part of the OAC's website, "Stop Weight Bias."[441] The purpose of this website was to promote pharmaceutical intervention for obesity. In addition, much like Novo's websites discussed above, Stop Weight Bias requires the user to provide all of their biographical information to access the "bias free image gallery."[442]

392. Defendants have used the unique targeting capabilities and viral nature of social media to further drive demand and promote pharmaceuticals as the right treatment for weight loss.[443]

393. Novo had long been a proponent of using analytics to target and maximize sales.[444] Novo's aggressive marketing included a number of different platforms, including over 4,000 marketing advertisements for Ozempic and similar weight-loss medications on Facebook and Instagram.[445]

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[439] https://www.truthaboutweight.com/understanding-excess-weight/my-weight-my-culture.html (last visited on Sept. 18, 2023).

[440] https://www.lilly.com/news/stories/combatting-weight-bias.

[441] https://stopweightbias.com/action/.

[442] https://stopweightbias.com/image-gallery/.

[443] https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html (last visited Sept. 18, 2023).

[444] "Utilizing Advanced Marketing Analytics for Sales Optimization – Peter Vester, Novo Nordisk" (Dec. 22, 2022) (last accessed 10.2.2024), available at https://www.youtube.com/watch?v=nCZR6wK7MlU.

[445] https://www.nbcnews.com/tech/internet/ozempic-weight-loss-drug-ads-instagram-wegovy-semaglutide-rcna88602 (last visited Sept. 18, 2023).

394. These platforms allow for invasive targeted advertising. For example, on Facebook, an advertiser can define the precise parameters of the audience they want to target (*e.g.*, young women who struggle with weight, etc.) and Facebook can push an advertisement out to that exact audience based on its data analytics and algorithm.[446] Instagram has similar features.

395. Social media advertising is also effective at targeting teenagers. The volume of weight loss drug advertisements and paid influencers is so high that Parents Together, a nonprofit focused on pushing news to parents, has issued an advisory to parents and provided talking points about how to navigate these advertisements with their teenager.[447] The organization warns parents that "Companies that make semaglutide weight loss drugs are explicitly targeting social media influencers to promote them, especially plus size and body positive fashion influencers who have large followings of young people."[448]

396. It is recognized by the medical community and literature that weight loss drugs are contributing to worsening eating disorders.[449] And adolescent girls are among the most susceptible to eating disorders.

397. As noted, Novo partnered directly with Meta and Instagram to run marketing campaigns. One diabetes marketing campaign achieved a dramatic 28% direct engagement rate

[446] https://www.facebook.com/business/ads/ad-targeting.

[447] https://parentstogetheraction.org/2024/03/06/parent-advisory-social-media-companies-push-weight-loss-drugs-like-ozempic-on-teens-despite-risks/

[448] https://parentstogetheraction.org/2024/03/06/parent-advisory-social-media-companies-push-weight-loss-drugs-like-ozempic-on-teens-despite-risks/

[449] Sazbo, Kopf and Syal, *Weight loss drugs like Wegovy may trigger eating disorders in some patients, doctors warn: Abuse of weight loss drugs is nothing new, but "nothing compares to the phenomenon that we're seeing right now with these GLP-1s,"* NBC News (July 31, 2024) available at https://www.nbcnews.com/health/mental-health/eating-disorders-increase-weight-loss-drugs-wegovy-zepbound-rcna162124.

with their polls.[450] This was a lauded result presented in a case study by Meta.

398. Marketing on social media, including Instagram and TikTok, often uses a hashtag. A hashtag is a word or phrase preceded by the # symbol that helps categorize and track content. When people or companies post content, they can add a hashtag which will make the content more searchable and help users find related posts. It can also help brands reach their target audience and optimize the brand's reach.

399. Novo's hashtags such as #Ozempic, #wegovyweightloss, #ozempicjourney all had hundreds of millions of views, representing the scope of its social media presence.

400. Lilly ran a similar social media marketing campaign about its drug Trulicity.[451]

401. As part of that social media campaign, Eli Lilly launched #Trulikeme which was "aimed to reduce the stigma surrounding diabetes while encouraging individuals to share their stories." This hashtag was launched on Instagram and Facebook and resulted in "thousands" of patients sharing their stories.[452]

402. These hashtags can also be used to facilitate engagement with the Defendants' website. For example, the hashtag #ItsBiggerThan, was an advertising campaign on Instagram that stated purpose was to educate the public about obesity and to change the conversation around weight "bias." This campaign was part of the partnership between Novo and It's Bigger Than Me. As part of the campaign, paid influencers would use the hashtag and then it would be linked back to Novo's website. All of these campaigns were intended to sell consumers on the idea that a pharmaceutical intervention was the best treatment for obesity, in this case by coopting the "body

[450] https://business.instagram.com/success/novo-nordisk (last visited Sept. 17, 2023).

[451] https://www.linkedin.com/pulse/eli-lillys-strategic-social-media-management-case-ahmed-dz6pf/ (last visited Nov. 12, 2024).

[452] https://www.linkedin.com/pulse/eli-lillys-strategic-social-media-management-case-ahmed-dz6pf/ (last visited Nov. 12, 2024)

positivity" movement.

4. Defendants Have Consistently Promoted Their GLP-1 RAs for Off-Label Use

403. As set forth repeatedly above, Defendants consistently promoted their GLP-1 RAs for weight loss even before they were approved for weight loss.

404. Novo's Ozempic was not approved for weight loss. Saxenda was approved for weight loss on December 23, 2014, and Wegovy was approved for weight loss on December 23, 2023.

405. Novo was not permitted to market Ozempic for weight loss without FDA approval for that specific indication,[453] but before Wegovy ever received separate approval for treatment of weight loss, Novo had already begun mentioning weight loss in their Ozempic marketing, advertising, commercials and other promotional materials.[454]

406. This did not go unnoticed by the Office of Prescription Drug Promotion ("OPDP") which helps enforce FDA regulations that drug promotions be truthful, balanced, and non-misleading.

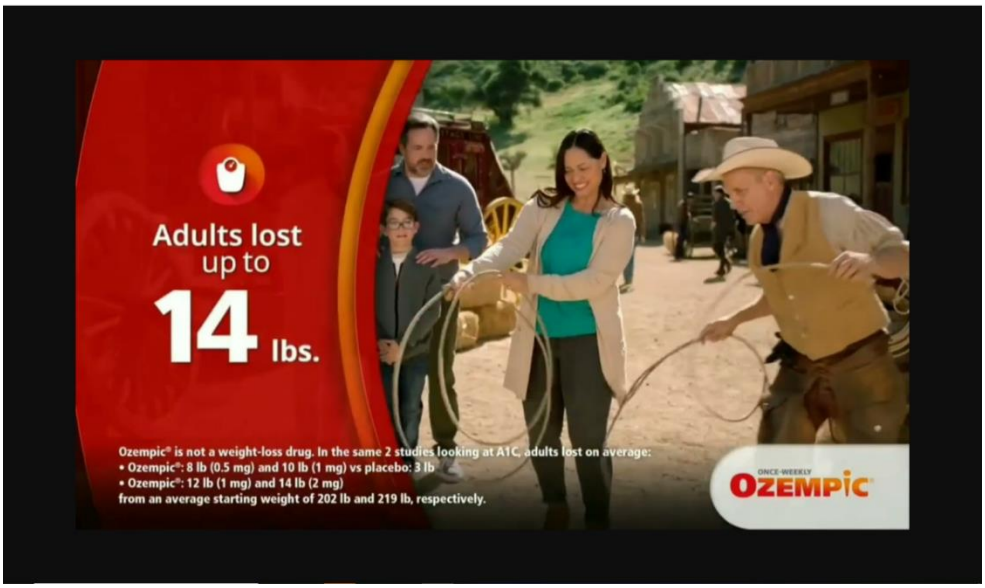
407. [redacted]

[453] https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html (last visited Sept. 18, 2023).

[454] *Id.*

[redacted].[455]

408. On July 30, 2018, Novo launched its first television ad for Ozempic to the tune of the 1970s hit pop song "Magic" by Pilot, wherein the Novo advertised that "adults lost on average up to 14 pounds" when taking Ozempic.[456]



409. Novo's Ozempic website has consistently touted weight loss:

- From 2018 to 2020: Novo's Ozempic.com claimed "[w]hile Ozempic is not for weight loss, you may also lose some weight."[457]
- From 2018 to 2019, Novo's OzempicPro.com homepage claimed "Superior weight reduction."[458]
- From 2018 to 2019, Novo's OzempicPro.com also claimed superior weight reduction vs. Trulicity and Bydureon; plus "more than double the weight

[455] [redacted]

[456] https://www.ispot.tv/ad/d6Xz/ozempic-oh (last visited Sept. 18, 2023).

[457] https://web.archive.org/web/20180820075728/https:/www.ozempic.com/FAQ/about-ozempic.html (last accessed Oct. 7, 2024).

[458] https://web.archive.org/web/20180826124503/https://www.ozempicpro.com/ (last accessed Oct. 7, 2024).

reduction for each dose comparison vs. Trulicity."[459]

- In 2020, Novo's OzempicPro.com homepage touted "significant weight reduction" with a link to "Examine weight data."[460]
- In 2021, Novo's Ozempic.com said "Ozempic may help you lose some weight" and "Adults taking Ozempic lost on average up to 12 pounds."[461]
- In 2021, Novo's Ozempic.com says "People lost more than double the weight on Ozempic vs Trulicity."[462]
- From 2022 to 2024, Novo's Ozempic.com homepage said: "Discover the Ozempic Tri-Zone," the third zone was "Ozempic may help you lose some weight."[463]
- From 2022 to 2024, Novo's Ozempic.com, under "What is Ozempic?" says "Adults taking Ozempic lost up to 14 pounds."[464]
- From 2022 to 2024, Novo's Ozempic.com said "People lost more than double the weight on Ozempic vs. Trulicity."[465]
- From 2022 to 2024, Novo's Novomedlink.com touted Ozempic Tri-Zone with "compelling weight loss."[466]
- In 2023, Novo's Ozempic.com FAQs page added a new disclaimer: "At this time, Novo Nordisk has not conducted studies to evaluate the effect on weight after discontinuation of Ozempic."

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[459] OzempicPro.com page name "Clinical Data" and "Ozempic and Weight" - from Wayback Machine.

[460] https://web.archive.org/web/20210730195708/https://www.ozempicpro.com/.

[461] https://web.archive.org/web/20211006213958/https:/www.ozempic.com/ (last accessed Oct. 7, 2024).

[462] *Id*.

[463] https://web.archive.org/web/20220808142658/https://www.ozempic.com/ (last accessed Oct. 8, 2024).

[464] https://web.archive.org/web/20220818181119/https://www.ozempic.com/why-ozempic/what-is-ozempic.html (last accessed Oct. 7, 2024).

[465] https://web.archive.org/web/20221003122256/https://www.ozempic.com/why-ozempic/diabetes-medicines-comparison.html (last accessed Oct. 7, 2024).

[466]https://web.archive.org/web/20240919183819/https://www.novomedlink.com/diabetes/products/treatments/ozempic.html (last accessed Oct. 7, 2024).

410. Novo has also promoted weight loss in its public statements. On March 28, 2022, Novo Nordisk announces Ozempic approval of higher dose (2 mg) for adults with type 2 diabetes; press release says: "it can help many patients lose some weight."[467]

411. Novo knew that Ozempic was being prescribed off-label.

412. Trulicity and Mounjaro were never approved for weight-loss. Zepbound was approved for weight loss on November 8, 2023.

413. Lilly was also well aware that its GLP-1 RAs were being prescribed off-label for weight loss.

414. Lilly repeatedly promoted weight loss on its website:

- On September 26, 2022, Lilly website stated Mounjaro is "designed for patients like Julia" who are "unhappy with her A1C and weight" and "with her T2D, she struggles with her weight despite her efforts with diet and exercise."[468]
- On September 26, 2022, Lilly Mounjaro website discussed recent studies suggest additional functions like regulating body weight.[469]
- On September 30, 2022, Lilly Mounjaro website stated "[u]nmatched weight results across clinical trials" (while noting "Mounjaro is not indicated for weight loss. Change in weight was as secondary endpoint.").[470]
- On September 30, 2022, Lilly Mounjaro HCP website includes significant clinical trial data comparing weight-loss to Ozempic.[471]

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[467] *See* https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approval-of-higher-dose-ozempic-2-mg-providing-increased-glycemic-control-for-adults-with-type-2-diabetes-301512209.html.

[468] https://web.archive.org/web/20220926035852/https://www.mounjaro.com/hcp/getting-patients-started (last accessed Oct. 18, 2024) (via Wayback) (22926W~1.PDF).

[469] https://web.archive.org/web/20220926024807/https://www.mounjaro.com/hcp/what-is-gip (last accessed Oct. 18, 2024) (22.9.26 Wayback Machine- Mounjaro Website on Regulating Body Weight.pdf).

[470] https://web.archive.org/web/20220930171231/https://www.mounjaro.com/hcp (last accessed Oct. 18, 2024) (22.9.30 Wayback Machine - Lilly HCP Website.pdf).

[471] https://web.archive.org/web/20220930171237/https://www.mounjaro.com/hcp/a1c-weight (last accessed Oct. 18, 2024).

- On January 27, 2023, Lilly Mounjaro website citing data on weight loss and leading with "Reset Your Expectations."[472]

- On January 27, 2023, Lilly Mounjaro website advertising that people on Mounjaro lost up to 25 lbs (while also stating Mounjaro is not a weight loss drug).[473]

415. Lilly's marketing also promoted off-label use. In addition to those previously discussed:

- On September 1, 2023, Lilly Mounjaro TV ad- Mounjaro Commercial #2 (2023); mentioning people lost up to 25 lbs.

- On September 25, 2023, Lilly Mounjaro Commercial #3 (2023) TV ad; mentioning people lost up to 25 lbs.

- On November 15, 2023, Lilly TV ad - Mounjaro Moments & Brittany's Story mentioning weight loss benefits. "I've also been able to lose weight, and I'm finding clothes in my closet that I haven't worn since I had my first kid. I just feel healthier these days."

5. Defendants Partnered with Telehealth Providers Making GLP-1 RAs More Accessible and Lowering Safeguards Against Off-Label Use

416. On October 1, 2019, Novo announced a partnership with Noom, a leading online weight loss platform, for "digital health solutions to help people with obesity lose weight and keep it off."[474]

417. In 2021, Novo participated in a $540 Million round of financing with Noom.[475]

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[472] https://web.archive.org/web/20230127014022/https://www.mounjaro.com/hcp/a1c-weight (last accessed Oct. 18, 2024) (23.1.27 Wayback- Mounjaro Website on Weight Loss Data and Reset Expectations.pdf).

[473] https://web.archive.org/web/20230131203653/https://www.mounjaro.com/ (last accessed Oct. 18, 2024) (January 27, 2023 Wayback- Mounjaro Website on People Lost 25 lbs.pdf).

[474] *See* https://www.distilnfo.com/lifesciences/2019/10/08/novo-nordisk-and-noom-to-partner-around-digital-health-solutions-to-help-people-with-obesity-lose-weight-and-keep-it-off-2/.

[475] https://www.businesswire.com/news/home/20210525005492/en/Noom-Announces-540-Million-in-Growth-Funding-to-Further-Accelerate-Expansion-of-its-Digital-Health-Platform

Novo currently lists, on the Novo Holdings website, that it has "venture investments" in Noom.[476]

418. Noom Med now provides to consumers, using physicians hired by Noom, prescriptions for GLP-1 RAs directly to patients.[477] Noom Med promotes off label usage of GLP-1 RAs on its website.[478] Noom currently has over 45 million users.[479]

419. Other telehealth providers mirrored Noom's approach offering prescriptions directly to consumers for GLP-1 RAs. This includes:

- Weight Watchers, who purchased telehealth startup Sequence for $132 Million so that it could provide weight loss medications to its subscribers.[480] There are currently over 3.5 Million Weight Watchers subscribers.[481]
- This also includes Calibrate, yet another telehealth provider for GLP-1 RAs, which raised $100 Million in capital funding from investors in 2021.

420. Collectively, the telehealth providers that Novo directly and indirectly partnered with and/or promotes account for approximately half of all weight loss prescriptions in 2022.[482]

421. Telehealth presents unique challenges with respect to GLP-1 RAs. Outside of the diabetes context, qualifying for GLP-1 RAs as a treatment for obesity requires only BMI and potential one additional health condition. BMI is a simple calculation that includes only weight

[476] https://novoholdings.dk/investments/noom/

[477] https://abcnews.go.com/GMA/Wellness/noom-joins-weight-watchers-offering-medications-wegovy-weight/story?id=99841160 (last visited on Sept. 18, 2023).

[478] https://www.noom.com/med/ (last visited on Sept. 18, 2023).

[479] https://exitsandoutcomes.com/free-excerpt-from-the-noom-report-a-45-million-moat/ (last visited Sept. 18, 2023).

[480] https://www.usatoday.com/story/news/health/2023/03/07/weightwatchers-sequence-wegovy-obesity-weight-loss-drugs/11415201002/ (last visited on Sept. 18, 2023).

[481] https://finance.yahoo.com/news/ww-international-inc-announces-first-200100340.html#:~:text=%E2%80%9CWe%20expect%20to%20end%202023,including%203.5%20million%20WeightWatchers%20subscribers. (last visited on Sept. 18, 2023).

[482] https://www.statnews.com/2023/08/10/wegovy-ozempic-weight-loss-telehealth-prescriptions/.

and height.[483] Without seeing a patient in person, these figures are dependent upon the inputs of the patient with a difference of 5 to 10 pounds of weight or 1 to 2 inches in height making the difference for drug eligibility. For this and other reasons, telehealth facilitates off-label usage.

422. Upon information and belief, these telehealth providers now provide access to GLP-1 RAs manufactured by both Novo and Lilly.

423. Lilly took accessibility even further when, on January 4, 2024, it launched LillyDirect, where patients can purchase Mounjaro and Zepbound through Lilly's portal.[484]

424. LillyDirect is comprised of a website which offers "Disease state and healthcare educational information to help empower and support patients on their care journeys" as well as LillyDirect Pharmacy Solutions, a digital pharmacy for select Lilly medicines powered by third party online pharmacy fulfillment services."

425. The LillyDirect website also connects patients with "independent" telehealth providers – FormHealth and 9amHealth—to facilitate prescriptions.[485]

426. Some experts have cautioned that Lilly offering Mounjaro and Zepbound via this website "is just an evolution of direct-to-consumer advertising" and will make it easier for the pharmaceutical giant to target patients with their products.[486]

427. The American College of Physicians released a statement that the organization "is

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[483] https://newsroom.uw.edu/resource/why-body-mass-index-doesnt-give-whole-health-picture (last visited Sept. 18, 2023).

[484] Blum, Dani, *As Eli Lilly Wades Into Telehealth for Weight Loss, Doctors Are Wary: The maker of Zepbound and Mounjaro launched a new platform to connect patients and prescribers*, NY Times (Jan. 5, 2024) available at https://www.nytimes.com/2024/01/05/well/weight-loss-tirzepatide-lilly-telehealth.html.

[485] https://lillydirect.lilly.com/telehealth/obesity.

[486] https://www.nytimes.com/2024/01/05/well/weight-loss-tirzepatide-lilly-telehealth.html (last accessed Oct. 10, 2024.

concerned by the development of websites that enable patients to order prescription medications directly from the drugmaker," adding that the approach "is primarily oriented around the use of telehealth services to prescribe a drugmaker's products."[487]

428. Telemedicine and other DTC services have the "potential to leave patients confused and misinformed about medications." Therefore, the American College of Physicians has stated that, for telemedicine services to take place "responsibly," there should be an "established and valid patient-physician relationship, or the care should happen in consultation with a physician who does have an established relationship with the patient."[488]

429. In an October 21, 2024 letter to Lilly, Senator Durbin raised concerns, relating to telehealth providers and their potential conflicts of interest. For example, the Senator wrote that the "launch of Eli Lilly's telehealth platform raises questions about the nature of Eli Lilly's relationship with its contracted telehealth prescribers." The letter details how in 2022, the Office of Inspector General for the HHS [("OIG")] issued a Special Fraud Alert to notify health care practitioners of the specific risks of schemes involving telehealth platforms. According to the Senator, the "nature of the LillyDirect platform" appears to reflect many aspects detailed in the OIG's warning for potential fraud.

430. Senator Durbin's letter also questions Lilly's partnership with telehealth provider FormHealth, detailing an Instagram post from FormHealth labeled "When do you start losing

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[487] https://www.nytimes.com/2024/01/05/well/weight-loss-tirzepatide-lilly-telehealth.html (last accessed Oct. 10, 2024).

[488] Atiq, Omar, *Internal Medicine Physicians Concerned by Direct-to-Consumer Pharmaceutical Sales of Prescription Medications*, American College of Physicians (Jan. 5, 2024) available at https://www.acponline.org/acp-newsroom/internal-medicine-physicians-concerned-by-direct-to-consumer-pharmaceutical-sales-of-prescription#:~:text=For%20telemedicine%20services%20to%20take,established%20relationship%20with%20the%20patient.

weight on Zepbound?" According to the Senator, the advertisement "appears to promote Eli Lilly's medications and erodes the appearance of independence between the telehealth company and Eli Lilly."

6. Defendants Used Coupon Programs and Other Discounts to Make Their GLP-1 RAs More Accessible for New Consumers

431. When Novo announced that they had started selling Ozempic in the United States, they touted the medication as a "new treatment option[]" that "addresses the concerns and needs of people with diabetes[.]" Novo offered an "Instant Savings Card to reduce co-pays to as low as $25 per prescription fill for up to two years."[489]

432. On May 24, 2022, Lilly's Mike Mason discussed a similar strategy of offering discounts and sample to market Mounjaro: "If patients are able to get access to it, who are able to have a good start on the medication, that just wonderfully supports your position in the marketplace. . . . [W]e will have a $25 copay cards, so people can get access at affordable price. We're going to be providing month-long samples at 2.5 milligram dose, so that patients can experience the product for a month at 2.5."[490] Lilly took a similar approach with Zepbound where they have offered single dose vials at a 50% discount when fulfilled through their online pharmacy.[491]

433. These programs allowed patients to get on the GLP-1 RAs without the significant cost barrier that comes with continued use. Of course, once the patient stops using the drug, they

[489] *See* BIOSPACE, *Novo Nordisk Launches Ozempic and Fiasp, Expanding Treatment Options for Adults With Diabetes* (Feb. 5, 2018), https://www.biospace.com/novo-nordisk-launches-ozempic-and-fiasp-expanding-treatment-options-for-adults-with-diabetes.

[490] Eli Lilly & Co Conf Presentation Call 2022524 DN000000002983664779.pdf.

[491] *See* https://www.ajmc.com/view/eli-lilly-expands-zepbound-access-with-discounted-single-dose-vials-self-pay-options (last accessed Oct. 9, 2024)

gain back the weight.

K. DEFENDANTS FAILED TO WARN OF THE SERIOUS RISKS OF THEIR GLP1-RA DRUGS AND DOWNPLAYED THESE RISKS IN THEIR UNPRECEDENTED MARKETING TO HEALTHCARE PROVIDERS AND PATIENTS

434. As set forth previously in this Complaint, Defendants knew, or should have known, based on preclinical trials, premarket clinical trials, post-market surveillance, and adverse event reports, that there was reasonable evidence of a causal association and of the causal association between the use of GLP-1 RAs and the risks of developing gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

435. Despite this knowledge, Defendants spent hundreds of millions of dollars to aggressively expand the market for the GLP-1 RAs while misleading users and healthcare providers about the serious dangers of the drugs.

436. Defendants purposefully downplayed, understated and ignored the health hazards and risks associated with using GLP-1 RAs.

437. They deceived healthcare providers and potential GLP-1 RA users by communicating positive information through the press, medical organizations and testimonials from social media influencers while expanding the definition of obesity and downplaying the known adverse and serious health effects of their GLP-1 RA drugs.

438. The FDA's Changes Being Effected ("CBE") process permits pharmaceutical

manufacturers to unilaterally update their labels without prior FDA approval, including by adding or strengthening warnings and descriptions of adverse reactions, and by deleting false or misleading claims.

439. Defendants' research into their products put them in a position to be become aware, in the post-approval context, of the risks and danger of the use of GLP-1 RAs, including the risks of of developing gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; vitamin deficiencies; dehydration and their sequelae.

440. Defendants were also obligated under 21 CFR §§310.305 and 314.80 to investigate each adverse event associated with their GLP-1 RAs, and Defendants failed to conduct such investigations reasonably, including by failing to take or record unsuccessful steps to seek additional information regarding serious unexpected adverse drug experiences.

441. Defendants likewise violated 21 CFR § 312.32 through their failure to review all information relevant to the safety of their GLP-1 RAs and report such information to the FDA.

442. As Defendants developed information regarding those risks and dangers after the FDA's initial approval of the original label, Defendants were required to make unilateral changes under the CBE process to these products' labels in order to warn physicians and consumers of those risks.

443. Defendants failed to warn doctors and consumers of these dangers.

444. Defendants intentionally withheld from or misrepresented to the FDA post-approval information concerning their GLP-1 RAs that was required to be submitted under the Federal Food, Drug, and Cosmetic Act. Had Defendants not withheld or misrepresented such information relating to the risks of GLP-1 RA use to the FDA, the FDA would have recommended that Defendants add warnings relating to the risks of the injuries suffered by Plaintiffs.

445. Despite developing this knowledge, Defendants did not disclose these risks and/or intentionally downplayed these risks in their labelling, promotion materials, marketing, advertising, and other public facing communications. Defendants' failure to disclose and/or intentional downplaying of these conditions prevented patients and doctors from taking appropriate precautions to reduce or mitigate the risk of these conditions. Defendants' failure deprived patients, like Plaintiffs, and doctors, like Plaintiffs' physicians, from having the full information necessary to weigh the risks and benefits of taking the Defendants' GLP-1 RAs.

1. The Sponsor of a Drug is Responsible for Ensuring the Safety of Its Drug and For Warning

446. The Sponsor of a drug is responsible for the safety of its product.

447. A drug company is responsible for alerting healthcare providers and patients of risks that are unknown or not well understood.

448. The Institute of Medicine has stated that FDA's ability to oversee drug safety is limited, especially after approval of a drug.

449. The Institute of Medicine wrote in a report entitled *The Future of Drug Safety: Promoting and Protecting the Health of the Public*:

450. "The drug safety system is impaired by the following factors: serious resource constraints that weaken the quality and quantity of the science that is brought to bear on drug

safety; an organizational culture in CDER (FDA Center for Drug Evaluation and Research) that is not optimally functional; and unclear and insufficient regulatory authorities particularly with respect to enforcement." The Report further stated that "FDA, contrary to its public health mission, and the pharmaceutical industry, contrary to its responsibility to the users of its products (and its shareholders), do not consistently demonstrate accountability and transparency to the public by communicating safety concerns in a timely and effective fashion."

451. The FDA has insufficient resources to monitor the 11,000 drugs on the market.

452. Manufacturers have access to information about their drugs, especially in the post-approval phase as new risks emerge, that is superior to the access that FDA has.

453. Uncommon risks or those that appear as common conditions, develop after long periods of time or have adverse impacts on special populations may go undetected in clinical trials.

454. If a drug company has reason to know the risks of a drug may result in adverse events, even if it develops that knowledge in the post-approval context, that company has a responsibility to investigate those risks and to provide necessary information healthcare providers.

455. The following FDA standards govern a manufacturer's duty to warn:

456. 21 C.F.R. § 201.57(c)(6): Warnings and precautions: "This section must describe clinically significant adverse reactions . . . the labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association of a serious hazard with a drug; a causal relationship need not have been definitely established . . ."

457. In addition, under 21 C.F.R. § 201.57(c)(6), the Warning and Precaution Section of prescription drug labels must "describe clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug), other potential safety hazards . . ."

458. It is a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times.

459. A manufacturer is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.

460. FDA's 2011 Guidance on Warnings in labeling advises: The WARNINGS AND PRECAUTION section is intended to identify and describe a discrete set of adverse reactions and other potential safety hazards that are serious or otherwise clinically significant because they have implications for prescribing decisions or for patient management."

461. FDA's Guidance also states, "Adverse reactions that do not meet the definition of a serious adverse reaction, but are otherwise clinically significant because they have implications for prescribing decisions or patient management, should also be included in the WARNINGS AND PRECAUTIONS section.

462. The medical literature discussing gastroparesis describes the distressing nature of the condition and its potential to profoundly limits a person's quality of life.[492]

2. The Labels for Defendants' GLP-1 RAs Were Inadequate at All Relevant Times From Launch to Present

a. Gastrointestinal Injuries

463. At all relevant times, the "Warnings and Precautions" sections of the Prescribing Information for Novo-Nordisk's Ozempic (semaglutide) and Rybelsus (semaglutide) omitted and continue to omit any "Warnings and Precautions" concerning gastroparesis, the potential for emergent care, hospitalization, long term treatment or death.

[492] *See generally, e.g.*, Lee et al, Health-Related Social Needs in Patients With Gastroparesis: Relationships to Symptom Severity and Quality of Life, 6 Gastro. Hep. Adv.48 (2023); Simons & Kline, Scoping review: the social and emotional impacts of gastroparesis, Transl. Gastroenterol. Hepatol. (2024).

464. At all relevant times, these drugs noted (under the heading "Acute Kidney Injury") that clinicians should "[m]onitor renal function in patients with renal impairment reporting severe adverse gastrointestinal reactions."

465. At all relevant times, Wegovy's (semaglutide) Prescribing Information stated that clinicians should "[m]onitor renal function when initiating or escalating doses of Wegovy in patients reporting severe adverse gastrointestinal reactions or in those with renal impairment reporting severe gastrointestinal reactions."

466. At all relevant times, this Wegovy Prescribing Information failed to state that these drugs have been associated with gastroparesis or other GI-related complications of similar acuity.

467. At all relevant times, Victoza (liraglutide) and Saxenda (liraglutide) stated similar warnings in the context of "Renal Impairment" in their warnings, but also failed to state any association with these drugs and gastroparesis or other GI-related complications of similar acuity.

468. At all relevant times, The "Adverse Reactions" sections of Novo-Nordisk's labels for Ozempic (semaglutide), Rybelsus (semaglutide), Wegovy (semaglutide) Victoza (liraglutide) and Saxenda (liraglutide) all inadequately referenced "common adverse reactions" including "nausea, vomiting, diarrhea, stomach (abdominal) pain, and constipation." These vague references provided no notice of the magnitude of these conditions effectively downplaying the risks while simultaneously failing to disclose gastroparesis or other GI-related complications. The vague and inadequate description of "common adverse reactions" inaccurately suggested these conditions will decrease over time and downplayed the intensity and range of conditions that patients face, including the potential for hospitalization, long-term damage to vital organs and the need for surgical intervention, disability and death.

469. Likewise, at all relevant times, the "Warnings and Precautions" sections of the

Prescribing Information for Eli-Lilly's drugs Trulicity (dulaglutide) and Mounjaro (tirzepatide) stated that use of the drugs "may be associated with gastrointestinal adverse reactions, sometimes severe" without disclosure that these adverse reactions may actually be symptoms of gastroparesis, which can be persistent, life-threatening, require hospitalization, lead to disabling secondary conditions or even death.

470. At all relevant times, the Warnings and Precautions section for Eli-Lilly's Zepbound (tirzepatide) stated a similarly deficient generalized statement in its "Warnings and Precautions" section of the Prescribing Information.

471. The vague and inadequate description of "gastrointestinal adverse reactions, sometimes severe" inaccurately suggested these conditions will decrease over time and downplayed the intensity and range of conditions that patients face, including the potential for hospitalization, long-term damage to vital organs and the need for surgical intervention, disability and death.

472. At all relevant times, the Mounjaro and Zepbound labels also downplayed the risk of gastroparesis with a statement that the drugs have "not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients" and similarly downplayed the seriousness of nausea, vomiting and/or diarrhea with the statement that the majority of these reactions occurred during dose escalation and decreased over time.

473. Further, the labels misleadingly suggested that the risk of delayed gastric emptying with tirzepatide always "diminishes over time" without acknowledging that other GLP1-RA drugs in the class that similarly delay gastric emptying have been shown to persistently delay gastric emptying well after dose escalation.

474. At all relevant times, the "Adverse Reactions" section of their labels, Eli-Lilly's Trulicity (dulaglutide), Mounjaro (tirzepatide), and Zepbound (tirzepatide) inadequately mentioned certain specific gastrointestinal disorders, including nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain. These vague references provide no notice of the magnitude of these conditions effectively downplaying the risks while simultaneously failing to mention gastroparesis or other GI-related complications of similar acuity.

475. The vague and inadequate description inaccurately suggested these conditions will decrease over time and downplayed the intensity and range of conditions that patients face, including the potential for emergent care of hospitalization, long-term damage to vital organs, the need for surgical intervention, disability and death.

476. Moreover, any references to the delay of gastric motility as part of the mechanism of action of Defendants' GLP-1 RAs did not warn patients and doctors that the Products could lead to a harmful delay in gastric emptying known as gastroparesis or that such conditions could last well after cessation of the GLP-1 RAs.

477. In November 2024, Defendants finally acknowledged some of the serious risks that can occur because of delayed gastric emptying with their GLP1-RA drugs. In November 2024, all Defendants added a warning to Section 5 of their drugs labels cautioning prescribers that reasonable evidence of a causal association exists with respect to their GLP-1 RA drugs and post-market reports of pulmonary aspiration in patients undergoing elective surgeries or procedures requiring general anesthesia or deep sedation who had residual gastric contents despite adherence to preoperative fasting recommendations. In other words, there is reasonable evidence of a causal association that the delay in gastric emptying caused by the drugs may lead to the retention of food

or liquid in the stomach after fasting, which presents the risk of food or liquid getting into the lungs.

478. Defendants' acknowledgement that delayed gastric emptying is not only a known mechanism of action of their GLP1-RA drugs but also a serious risk of the drugs should have been disclosed years earlier.

479. Prior to 2023, at least 89 cases of gastroparesis that were life-threatening, required hospitalization or medical intervention, and/or led to disability or death were reported.[493]

480. Between 2008 and 2024, six case reports were published describing patients on GLP1 RA drugs who developed gastroparesis and required hospitalization, including for endoscopic bezoar removal and botulinum toxin injections.[494]

481. As cited above, peer-reviewed medical literature, Clinical Guidelines, and commonly used medical references acknowledge the risk of gastroparesis with GLP1-RA drugs.[495]

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[493] FDA FAERS database events for Defendant's drugs Mounjaro, Ozempic, Wegovy, Saxenda, Victoza and Trulicity. FAERS data can be accessed from https://www.fda.gov/drugs/fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard.

[494] Cure, *et al.*, *Exenatide and Rare Adverse Events*, 358 NEJM 1969 (2008) (patient treated with exenatide developed gastroparesis; developed bezoars on two occasions that were removed endoscopically and required injections of botulinum toxin); Ishihara, *et al*., *Suspected Gastroparesis With Concurrent Gastroesophageal Reflux Disease Induced by Low-Dose Liraglutide*, Cureus (2022) (patient treated with liraglutide hospitalized for six days due to gastroparesis); Rai et al, Liraglutide-induced Acute Gastroparesis, Cureus (2022) (patient treated with liraglutide admitted to hospital due to gastroparesis); Almustanyir, *et al*., *Gastroparesis with the initiation of Liraglutide,* Cureus (patient treated with liraglutide hospitalized for three days due to gastroparesis); Shemies, *et al*., *Semaglutide Induced Gastric Outlet Obstruction*, 45 Teikyo Med. J. 6743 (2022) (patient treated with semaglutide hospitalized for five days due to gastroparesis); Chaudhry, *et al.*, *Tendency of semaglutide to induce gastroparesis*, Cureus (2024) (patient treated with semaglutide hospitalized due to gastroparesis).

[495] UpToDate, Dungan & DeSantis, *Glucagon-like peptide 1-based therapies for the treatment of type 2 diabetes mellitus* (2024), https://www.uptodate.com/contents/glucagon-like-peptide-1-based-therapies-for-the-treatment-of-type-2-diabetes-mellitus;, StatPearls, Reddivari & Mehta, Gastroparesis (2024), https://www.ncbi.nlm.nih.gov/books/NBK551528/; Hui, *et al*., Approach to Internal Medicine (5th ed.); Huppert's Notes, Pathophysiology and Clinical Pearls for Internal

482. At all relevant times, Defendants did not fully inform the FDA about the justification for the warnings set forth above and required by state law.

483. At all relevant times, Defendants failed to reevaluate and re-assess the risks of gastroparesis in light of newly available information.

484. At all relevant times, Defendants failed to disclose information regarding the serious risks of gastroparesis with their GLP1-RA drugs.

485. At all relevant times, Defendants failed to evaluate safety data in their possession and reassess such data in light of newly acquired information.

486. Had Defendants affirmatively and specifically presented such safety information regarding the risk of gastroparesis with their GLP1-RA drugs to FDA, FDA would have permitted Defendants to add the risk of gastroparesis and/or harmful delayed gastric emptying to the labels of their GLP1-RA drugs.

487. This failure to adequately warn patients and healthcare providers has caused or substantially contributed to physical injury and emotional suffering, and resulted in the need for emergent care, hospitalizations requiring among other treatments, parenteral nutrition, hydration, pharmacologic treatments and surgical intervention.

488. GLP-1 RAs and the rapid weight loss reasonably associated with their use also create the risk of micronutrient deficiencies and unfavorable changes to body composition.[496] Individuals who go through rapid weight loss may suffer deficiencies in nutrients including

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Medicine (2024 ed.), McCallum, *et al*., Gastroparesis Pathophysiology, Clinical Presentation, Diagnosis and Treatment (1st ed.); Tack & Camilleri, New developments in the treatment of gastroparesis and functional dyspepsia, 43 Current Opinion in Pharmacology111 (2018); Lacy, *et al*., AGA Clinical Practice Update on Management of Medically Refractory Gastroparesis: Expert Review, 20 Clinical Gastroenterology and Hepatology 491 (2022).

[496] O'Donnell, Severe Micronutrient Deficiencies in RYGB Patients, Nutrition Issues in Gastroenterology, Series #100, Practical Gastroenterology, Nov. 2011, at 24.

thiamine, Vitamin C, and Vitamin D, which deficiencies can in turn cause a variety of additional symptoms.[497] Defendants' labels do not and did not warn of the risk of these injuries, and that omission prevented Plaintiffs and their doctors from making informed decisions about their potential use of GLP-1 RAs or taking steps to mitigate this potential risk.

489. Gastroparesis is also reasonably associated with micronutrient deficiencies.[498] Defendants' failure to warn of this potential risk prevented Plaintiffs and their doctors from making informed decisions about their potential use of GLP-1 RAs or taking steps to mitigate this potential risk.

b. Cyclical Vomiting

490. As discussed above, Defendants knew or should have known that reasonable evidence of a causal association between their GLP-1 RAs and severe and debilitating vomiting and related injuries existed but at no time did the labels for the GLP-1 RAs or any accompanying materials identify the risk of debilitating and life-threatening cyclical vomiting.

491. Likewise, the "Adverse Reactions" sections of Novo-Nordisk's labels for Ozempic (semaglutide), Rybelsus (semaglutide), Wegovy (semaglutide) Victoza (liraglutide) and Saxenda (liraglutide) each inadequately reference "common adverse reactions" including "nausea, vomiting, diarrhea, stomach (abdominal) pain, and constipation." These references provide no notice of the magnitude of these conditions effectively downplaying the risks while simultaneously failing to disclose debilitating cyclical vomiting. The vague and inadequate description of "common adverse reactions" inaccurately suggested these conditions will decrease over time and downplayed the intensity and range of conditions that patients face, including the potential for

[497] *Id.* at 14.

[498] Ogorek et al, Idiopathic Gastroparesis is Associated with a Multiplicity of Severe Dietary Deficiencies, Am. J. Gastroenterology, Vol. 86, No. 4, 1991, at 426.

hospitalization, long-term damage to vital organs and the need for surgical intervention, disability and death.

492. Defendants' failure further deprived patients and doctors alike from having the full information necessary to weigh the risks and benefits of taking the Defendants' GLP-1 RAs.

493. At all relevant times, Defendants did not fully inform the FDA about the justification for the warnings set forth above and required by state law.

494. At all relevant times, Defendants failed to reevaluate and re-assess the risks of cyclical vomiting in light of newly available information.

495. At all relevant times, Defendants failed to disclose information regarding the serious risks of cyclical vomiting with their GLP1-RA drugs.

496. At all relevant times, Defendants failed to evaluate safety data in their possession and reassess such data in light of newly acquired information.

497. Had Defendants affirmatively and specifically presented such safety information regarding the risk of cyclical vomiting with their GLP1-RA drugs to FDA, FDA would have permitted Defendants to add the risk of cyclical vomiting to the labels of their GLP1-RA drugs.

498. This failure to adequately warn patients and healthcare providers has caused or substantially contributed to physical injury and emotional suffering, and resulted in the. need for emergent care, hospitalizations requiring among other treatments, parenteral nutrition, hydration, pharmacologic treatments and surgical intervention.

c. Gallbladder Disease

499. Defendants knew or should have known that GLP-1 RAs posed significant risks of gallbladder-related complications, including cholelithiasis, cholecystitis, and the need for cholecystectomy, but Defendants failed to provide adequate warnings to physicians and patients for years.

500. Ultimately, the label updates, which came long after these risks had been clearly identified, failed to fully convey the potential for serious and recurring gallbladder-related complications. Instead of providing comprehensive warnings, the labels merely referred to the risk of "Acute Gallbladder Disease," an inadequate description that downplayed the severity and range of conditions that patients faced, including the potential for long-term damage and the need for surgical intervention.

501. The eventual updates to the labeling for these drugs merely warned about acute gallbladder injury and did not adequately address the potential for severe and debilitating complications. These warnings came too late for many patients. Below are the specific label warnings issued:

- **Mounjaro** (May 2022): "Acute Gallbladder Disease: Has occurred in clinical trials. If cholelithiasis is suspected, gallbladder studies and clinical follow-up are indicated."[499]
- **Ozempic** (March 2022): "Acute Gallbladder Disease: If cholelithiasis or cholecystitis are suspected, gallbladder studies are indicated."[500]
- **Rybelsus** (June 2022): "Acute Gallbladder Disease: If cholelithiasis or cholecystitis are suspected, gallbladder studies are indicated."[501]
- **Saxenda** (December 2014): "Acute Gallbladder Disease: If cholelithiasis or cholecystitis are suspected, gallbladder studies are indicated."[502]
- **Trulicity** (June 2022): "Acute Gallbladder Disease: If cholelithiasis or

[499] Mounjaro, Eli Lilly and Company, 2022, *"Warnings and Precautions: Acute Gallbladder Disease: Has occurred in clinical trials. If cholelithiasis is suspected, gallbladder studies and clinical follow-up are indicated. (5.8)."*

[500] Ozempic, *Novo Nordisk Inc., 2022, "Warnings and Precautions: Acute Gallbladder Disease: If cholelithiasis or cholecystitis are suspected, gallbladder studies are indicated (5.8)."*

[501] Rybelsus, *Novo Nordisk Inc., 2022, "Warnings and Precautions: Acute Gallbladder Disease: If cholelithiasis or cholecystitis are suspected, gallbladder studies are indicated (5.7)."*

[502] Saxenda, *Novo Nordisk Inc., 2014, "Warnings and Precautions: Acute Gallbladder Disease: If cholelithiasis or cholecystitis are suspected, gallbladder studies are indicated (5.3)."*

cholecystitis are suspected, gallbladder studies are indicated."[503]

- **Wegovy** (June 2021): "Acute Gallbladder Disease: Has occurred in clinical trials. If cholelithiasis is suspected, gallbladder studies and clinical follow-up are indicated."[504]

- **Zepbound** (November 2023): "Acute Gallbladder Disease: Has been reported in clinical trials. If cholecystitis is suspected, gallbladder studies and clinical follow-up are indicated."[505]

502. The warnings were issued only after continuous yearly increases in the total number of adverse events from 2014 to 2022. The following chart shows data from the FAERS system that details the number of reported adverse events by year for GLP-1 RAs from 2010 to 2024:

Case Count by Received Year

Category	Number of Cases	Percentage
2024	30,683	17.62%
2023	33,962	19.50%
2022	19,899	11.43%
2021	16,804	9.65%
2020	14,051	8.07%
2019	11,315	6.50%
2018	10,573	6.07%
2017	7,906	4.54%
2016	6,922	3.97%
2015	5,466	3.14%
2014	1,533	0.88%
2013	1,991	1.14%
2012	4,998	2.87%
2011	5,344	3.07%
2010	2,701	1.55%
Totals	**174,148**	**100.00%**

[506]

[503] Trulicity, *Eli Lilly and Company, 2022, "Warnings and Precautions: Acute Gallbladder Disease: If cholelithiasis or cholecystitis are suspected, gallbladder studies are indicated (5.8)."*

[504] Wegovy, *Nov Nordisk Inc., 2021, "Warnings and Precautions: Acute Gallbladder Disease: Has occurred in clinical trials. If cholelithiasis is suspected, gallbladder studies and clinical follow-up are indicated (5.3)."*

[505] Zepbound, *Eli Lilly and Company, 2023, "Warnings and Precautions: Acute Gallbladder Disease: Has been reported in clinical trials. If cholecystitis is suspected, gallbladder studies and clinical follow-up are indicated. (5.4)."*

[506] FDA ADVERSE EVENTS REPORTING SYSTEM (FAERS) *Public Dashboard*, https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/8eef7d83-7945-4091-b349-e5c41ed49f99/state/analysis, U.S FOOD AND DRUG ADMINISTRATION.

503. Defendants' failure further deprived patients and doctors alike from having the full information necessary to weigh the risks and benefits of taking the Defendants' GLP-1 RAs.

504. At all relevant times, Defendants did not fully inform the FDA about the justification for the warnings set forth above and required by state law.

505. At all relevant times, Defendants failed to reevaluate and re-assess the risks of gallbladder-related complications in light of newly available information.

506. At all relevant times, Defendants failed to disclose information regarding the serious risks of gallbladder-related complications with their GLP1-RA drugs.

507. Had Defendants affirmatively and specifically presented such safety information regarding the risk of gallbladder-related complications with their GLP1-RA drugs to FDA, FDA would have permitted Defendants to add the risk of gallbladder-related complications to the labels of their GLP1-RA drugs.

508. This failure to adequately warn patients and healthcare providers has directly contributed to severe and debilitating complications, including unnecessary surgeries, prolonged hospitalizations, and significant physical and emotional suffering.

d. Deep Vein Thrombosis ("DVT") and related Pulmonary Embolism ("PE")

509. As discussed above, Defendants knew, or should have known that there was reasonable evidence of a causal association between use of their GLP-1 RAs and deep vein thrombosis ("DVT") and related pulmonary embolism ("PE") but at no time did the labels for the GLP-1 RAs or any accompanying materials identify the risk of DVT and/or PE.

510. Defendants' failure to include these conditions in the labels prevented patients and doctors from appropriately taking precautions to reduce or mitigate the risk of these conditions.

511. At all relevant times, Defendants did not fully inform the FDA about the

justification for the warnings set forth above and required by state law.

512. At all relevant times, Defendants failed to reevaluate and re-assess the risks of DVT and PE in light of newly available information.

513. At all relevant times, Defendants failed to disclose information regarding the serious risks of DVT and PE with their GLP1-RA drugs.

514. Had Defendants affirmatively and specifically presented such safety information regarding the risk DVT and PE with their GLP1-RA drugs to FDA, FDA would have permitted Defendants to add the risks of DVT and PE to the labels of their GLP1-RA drugs.

515. Defendants' failure further deprived patients and doctors alike from having the full information necessary to weigh the risks and benefits of taking the Defendants' GLP-1 RAs.

e. Bowel/Intestinal Blockage

516. As discussed above, Defendants knew or should have known that there was reasonable evidence of a causal association and that there was reasonable evidence of a causal association between use of their GLP-1 RAs and the development of bowel and/or intestinal blockage, but at no time did the labels for the GLP-1 RAs or any accompanying materials warn of the potential risk of bowel and/or intestinal blockage.

517. Defendants' failure to warn of these potential risks prevented patients and doctors from making and informed decision that could have resulted in drug not being recommended, prescribed and or used and prevented doctors and patients from otherwise appropriately taking precautions to reduce or mitigate the risk of the risk of these conditions.

518. As discussed above, Defendants knew, or should have known there was reasonable evidence of a causal association between GLP-1 RAs and bowel or intestinal blockage but at no time did the labels for the GLP-1 RAs or any accompanying materials identify these risks.

519. Defendants' failure to include these conditions in the labels prevented patients and

doctors from appropriately taking precautions to reduce or mitigate the risk of these conditions.

520. At all relevant times, Defendants did not fully inform the FDA about the justification for the warnings set forth above and required by state law.

521. At all relevant times, Defendants failed to reevaluate and re-assess the risks of bowel or intestinal blockage in light of newly available information.

522. At all relevant times, Defendants failed to disclose information regarding the serious risks of bowel or intestinal blockage with their GLP1-RA drugs.

523. Had Defendants affirmatively and specifically presented such safety information regarding the risk bowel or intestinal blockage with their GLP1-RA drugs to FDA, FDA would have permitted Defendants to add the risks of bowel or intestinal blockage to the labels of their GLP1-RA drugs.

524. Defendants' failure further deprived patients and doctors alike from having the full information necessary to weigh the risks and benefits of taking the Defendants' GLP-1 RAs.

f. Ileus

525. Defendants knew or should have known that there was reasonable evidence of a causal association and that that there was reasonable evidence of a causal association between the use of GLP-1 receptor agonists and the development of ileus, Defendants failed to provide adequate warnings to physicians and patients.

526. On September 22, 2023, the FDA instituted a safety-related labeling change to Ozempic, adding ileus as a Postmarketing experience adverse reaction in Section 6 of the label. Subsequently, ileus was added to the post-marketing experience section of Defendants' other GLP1-RAs.

527. Even then, the label update, which came long after these risks had been clearly identified, failed to fully convey the potential for serious and recurring ileus complications.

528. As discussed above, Defendants knew, or should have known that reasonable evidence of a causal association between their GLP1-RA drugs and ileus existed but at no time Defendants warn of this risk in section 5 of their labels.

529. Defendants' failure to include this condition in the labels prevented patients and doctors from appropriately taking precautions to reduce or mitigate the risk of these conditions.

530. At all relevant times, Defendants did not fully inform the FDA about the justification for the warnings set forth above and required by state law.

531. At all relevant times, Defendants failed to reevaluate and re-assess the risks of ileus in light of newly available information.

532. At all relevant times, Defendants failed to disclose information regarding the serious risks of ileus with their GLP1-RA drugs in the Warning and Precaution section of their labels.

533. Had Defendants affirmatively and specifically presented such safety information regarding the risk of ileus with their GLP1-RA drugs to FDA, FDA would have permitted Defendants to add the risk of ileus to the Warning and Precaution section (section 5) of the labels of their GLP1-RA drugs.

534. Defendants' failure to include these conditions in the Warning and Precaution section of their labels prevented patients and doctors from appropriately taking precautions to reduce or mitigate the risk of these conditions.

535. Defendants' failure further deprived patients and doctors alike from having the full information necessary to weigh the risks and benefits of taking the Defendants' GLP-1 RAs.

g. Esophageal Injury

536. As discussed above, Defendants knew, or should have known that there was reasonable evidence of a causal association between use of their GLP-1 RAs and esophageal injury

but at no time did the labels for the GLP-1 RAs or any accompanying materials identify the risk of esophageal injury.

537. Defendants' failure to include these conditions in the labels prevented patients and doctors from appropriately taking precautions to reduce or mitigate the risk of these conditions.

538. At all relevant times, Defendants did not fully inform the FDA about the justification for the warnings set forth above and required by state law.

539. At all relevant times, Defendants failed to reevaluate and re-assess the risks of esophageal injury in light of newly available information.

540. At all relevant times, Defendants failed to disclose information regarding the serious risks of esophageal injury with their GLP1-RA drugs.

541. Had Defendants affirmatively and specifically presented such safety information regarding the risk of esophageal injury with their GLP1-RA drugs to FDA, FDA would have permitted Defendants to add the risk of esophageal injury to the labels of their GLP1-RA drugs.

542. Defendants' failure further deprived patients and doctors alike from having the full information necessary to weigh the risks and benefits of taking the Defendants' GLP-1 RAs.

h. Muscle Wasting

543. As discussed above, Defendants knew, or should have known that there was reasonable evidence of a causal association between their GLP-1 RAs and muscle wasting but at no time did the labels for the GLP-1 RAs or any accompanying materials identify the risk of muscle wasting.

544. Defendants' failure to include these conditions in the labels prevented patients and doctors from appropriately taking precautions to reduce or mitigate the risk of these conditions.

545. At all relevant times, Defendants did not fully inform the FDA about the justification for the warnings set forth above and required by state law.

546. At all relevant times, Defendants failed to reevaluate and re-assess the risks of muscle wasting in light of newly available information.

547. At all relevant times, Defendants failed to disclose information regarding the serious risks of muscle wasting with their GLP1-RA drugs.

548. Had Defendants affirmatively and specifically presented such safety information regarding the risk of muscle wasting with their GLP1-RA drugs to FDA, FDA would have permitted Defendants to add the risk of muscle wasting to the labels of their GLP1-RA drugs.

549. Defendants' failure further deprived patients and doctors alike from having the full information necessary to weigh the risks and benefits of taking the Defendants' GLP-1 RAs.

i. Dehydration

550. As discussed above, Defendants knew, or should have known that there was reasonable evidence of a causal association between their GLP-1 RAs and dehydration but at no time did the labels for the GLP-1 RAs or any accompanying materials identify the risk of dehydration.

551. At all relevant times, Defendants did not fully inform the FDA about the justification for the warnings set forth above and required by state law.

552. At all relevant times, Defendants failed to reevaluate and re-assess the risks of dehydration in light of newly available information.

553. At all relevant times, Defendants failed to disclose information regarding the serious risks of dehydration with their GLP1-RA drugs.

554. Had Defendants affirmatively and specifically presented such safety information regarding the risk of dehydration with their GLP1-RA drugs to FDA, FDA would have permitted Defendants to add the risk of Wernicke's to the labels of their GLP1-RA drugs.

555. Defendants' failure to include these conditions in the labels prevented patients and

doctors from appropriately taking precautions to reduce or mitigate the risk of these conditions.

556. Defendants' failure further deprived patients and doctors alike from having the full information necessary to weigh the risks and benefits of taking the Defendants' GLP-1 RAs.

j. Ischemic Bowel

557. As discussed above, Defendants knew, or should have known that there was reasonable evidence of a causal association between their GLP-1 RAs and ischemic bowel but at no time did the labels for the GLP-1 RAs or any accompanying materials identify the risk of ischemic bowel.

558. At all relevant times, Defendants did not fully inform the FDA about the justification for the warnings set forth above and required by state law.

559. At all relevant times, Defendants failed to reevaluate and re-assess the risks of ischemic bowel in light of newly available information.

560. At all relevant times, Defendants failed to disclose information regarding the serious risks of ischemic bowel with their GLP1-RA drugs.

561. Had Defendants affirmatively and specifically presented such safety information regarding the risk of ischemic bowel with their GLP1-RA drugs to FDA, FDA would have permitted Defendants to add the risk of ischemic bowel to the labels of their GLP1-RA drugs.

562. Defendants' failure to include these conditions in the labels prevented patients and doctors from appropriately taking precautions to reduce or mitigate the risk of these conditions.

563. Defendants' failure further deprived patients and doctors alike from having the full information necessary to weigh the risks and benefits of taking the Defendants' GLP-1 RAs.

k. Necrotizing Pancreatitis

564. As discussed above, Defendants knew, or should have known that there was reasonable evidence of a causal association between their GLP-1 RAs and necrotizing pancreatitis

but at no time did the labels for the GLP-1 RAs or any accompanying materials identify the risk of necrotizing pancreatitis.

565. At all relevant times, Defendants did not fully inform the FDA about the justification for the warnings set forth above and required by state law.

566. At all relevant times, Defendants failed to reevaluate and re-assess the risks of necrotizing pancreatitis in light of newly available information.

567. At all relevant times, Defendants failed to disclose information regarding the serious risks of necrotizing pancreatitis with their GLP1-RA drugs.

568. Had Defendants affirmatively and specifically presented such safety information regarding the risk of necrotizing pancreatitis with their GLP1-RA drugs to FDA, FDA would have permitted Defendants to add the risk of necrotizing pancreatitis to the labels of their GLP1-RA drugs.

569. Defendants' failure to include these conditions in the labels prevented patients and doctors from appropriately taking precautions to reduce or mitigate the risk of these conditions.

570. Defendants' failure further deprived patients and doctors alike from having the full information necessary to weigh the risks and benefits of taking the Defendants' GLP-1 RAs.

l. Wernicke's encephalopathy

571. As discussed above, Defendants knew, or should have known that there was reasonable evidence of a causal association between their GLP-1 RAs and Wernicke's encephalopathy but at no time did the labels for the GLP-1 RAs or any accompanying materials identify the risk of Wernicke's.

572. At all relevant times, Defendants did not fully inform the FDA about the justification for the warnings set forth above and required by state law.

573. At all relevant times, Defendants failed to reevaluate and re-assess the risks of

dehydration in light of newly available information.

574. At all relevant times, Defendants failed to disclose information regarding the serious risks of Wernicke's with their GLP1-RA drugs.

575. Had Defendants affirmatively and specifically presented such safety information regarding the risk of Wernicke's with their GLP1-RA drugs to FDA, FDA would have permitted Defendants to add the risk of Wernicke's to the labels of their GLP1-RA drugs.

576. Defendants' failure to include these conditions in the labels prevented patients and doctors from appropriately taking precautions to reduce or mitigate the risk of these conditions.

577. Defendants' failure further deprived patients and doctors alike from having the full information necessary to weigh the risks and benefits of taking the Defendants' GLP-1 RAs.

m. Pulmonary Aspiration

578. As discussed above, Defendants knew, or should have known that there was reasonable evidence of a causal association between use of their GLP-1 RAs and pulmonary aspiration but at no time did the labels for the GLP-1 RAs or any accompanying materials identify the risk of pulmonary aspiration.

579. On November 6, 2024, the FDA required that Defendants update the labels for liraglutide (Saxenda, Victoza), semaglutide (Ozempic, Rybelsus, Wegovy) and tirzepatide (Mounjaro, Zepbound) with a warning about pulmonary aspiration during general anesthesia or deep sedation.

580. The eventual updates to the labeling for these drugs merely warned about pulmonary aspiration during general anesthesia or deep sedation and did not adequately address the potential for severe and debilitating complications or the risks associated with unplanned surgical procedures. These warnings came too late for many patients.

581. At all relevant times, Defendants did not fully inform the FDA about the

justification for the warnings set forth above and required by state law.

582. At all relevant times, Defendants failed to reevaluate and re-assess the risks of pulmonary aspiration and severe and debilitating complications in light of newly available information.

583. At all relevant times, Defendants failed to disclose information regarding the serious risks of pulmonary aspiration and severe and debilitating complications with their GLP1-RA drugs.

584. Had Defendants affirmatively and specifically presented such safety information regarding the risk of pulmonary aspiration and the potential for severe and debilitating complications with their GLP1-RA drugs to FDA, FDA would have permitted Defendants to add the risk of pulmonary aspiration and the potential for severe and debilitating complications to the labels of their GLP1-RA drugs.

* * *

585. Upon information and belief, as a result of Defendants' inadequate warnings, the medical community at large, and Plaintiffs' prescribing physicians in particular, were not aware that GLP-1 RAs can cause gastroparesis, gastroenteritis, cyclical vomiting, bowel/intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, esophageal injury, bowel injury, intraoperative aspiration, muscle wasting, vitamin deficiencies, dehydration, and their sequelae, nor were they aware that "common adverse reactions" listed on the GLP-1 RAs' labels might be symptoms of more serious conditions, including gastroparesis, gastroenteritis, ileus, bowel/intestinal obstruction/blockage, bowel injury, gallbladder problems, and esophageal injury.

586. Upon information and belief, had Defendants adequately warned Plaintiffs'

prescribing physicians of reasonable evidence of a causal association between GLP-1 RAs and gastroparesis, gastroenteritis, cyclical vomiting, bowel/intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, esophageal injury, bowel injury, intraoperative aspiration, muscle wasting, vitamin deficiencies, dehydration, and their sequelae, then the physicians' prescribing decisions would have changed, either by not prescribing the GLP-1 RAs, or by monitoring Plaintiffs' health for symptoms of the conditions listed above, and discontinuing the GLP-1 RA's when such symptoms started.

587. By reason of the foregoing acts and omissions, Plaintiffs were and still are caused to suffer from gastroparesis, gastroenteritis, cyclical vomiting, bowel/intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, esophageal injury, bowel injury, intraoperative aspiration, muscle wasting, vitamin deficiencies, dehydration, and their sequelae, which resulted in severe and debilitating personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences and/or dying.

3. Defendants' Marketing of GLP-1 RAs Was Intentionally Deceptive and Misleading and Lacked Fair Balance

588. Defendants' extensive multifaceted advertising, marketing and promotion of GLP-1 RAs discussed at length above consistently highlighted and overstated the weight loss benefits of taking a GLP-1 RA while failing to disclose the risks identified with those drugs and concealing other information that would be material to any Plaintiff and their physician in weighing the risks and benefits of taking a GLP-1 RA.

589. Defendants did not disclose and/or minimized the risks of developing gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.In addition, Defendants intentionally omitted other facts that they knew to be true from their labels, physician communications, marketing, website, public statements, and other public facing communications. These documents omit facts that include: (1) the average person only loses a small percentage of their body weight while on a GLP-1 RA; (2) GLP-1 RAs are not effective for everyone; (3) patients gain the weight back when they stop taking the GLP-1 RA (*i.e.*, patients have to stay on the drug forever); (4) the weight loss achieved while on a GLP-1 RA is not a healthy weight loss; (5) when a patient regains the weight loss achieved while on a GLP-1 RA, they are typically less healthy than when they began the medication; and (6) many people stop taking a GLP-1 RA relatively quickly because of trouble tolerating the drugs. These facts are critical to the balancing of risks and benefits facing most patients.

a. Average Weight Loss Is Modest

590. Studies show that the real number are much lower. Measured across the first 12 weeks of the drug, when most people are on the drug, the numbers are closer to 3.6% to 5.9% of body weight.[507] On July 8, 2024, a JAMA Internal Medicine article suggested that both Novo and

[507] *See* https://zepbound.lilly.com/ for Lilly inference and https://www.wegovy.com/about-wegovy/why-wegovy.html for Novo Nordisk.

Lilly overstated the weight loss benefits of their drug in advertisements. Over a year's time, those on tirzepatide (Mounjaro/Zepbound) lost an average of 15.3% of their body weight compared to 8.3% for semaglutide (Ozempic/Wegovy) users. Only 18% of those on semaglutide reported a weight loss of at least 15% of their body weight after one year of treatment.[508] More importantly, Novo's claim that their drugs create lasting weight loss are also misleading: their own data shows that only 9.4% of patients on the highest dose available sustain weight loss over a four year period.[509]

b. Non-responders

591. Some research suggests that patients taking semaglutide (*i.e.*, Ozempic and Wegovy) "found about 14% of patients lost less than 5% of their body weight and one-third lost less than 10%" while a separate trial focused on tirzepatide (Mounjaro and Zepbound) "demonstrated similar results."[510] Notably, the article discussing the research states that "Wegovy and Zepbound have been approved by the FDA for weight loss, while Ozempic and Mounajro have been prescribed for that purpose in an off-label fashion."

c. Patients Must Remain on the Drug to Sustain Weight Loss

592. For those who lose weight, they typically need to stay on the drug forever to maintain the weight loss.[511] A Medscape article from March of 2024 explains that when "patients

[508] *See* https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2821080 (last accessed Oct. 17, 2024).

[509]https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/cmd/2024/P5-Obesity-Care.pdf

[510] Carbajal, Erica, *Up to 15% of patients on weight loss drugs may be 'non-responders*, Becker's Hospital Review (April 1, 2024) available at https://www.beckershospitalreview.com/glp-1s/up-to-15-of-patients-on-weight-loss-drugs-non-responders.html.

[511] https://www.psychologytoday.com/ie/blog/the-neuroscience-of-eating-disorders/202303/ozempic-and-wegovy-is-semaglutide-a-miracle-weight (last visited on Sept. 18, 2023).

stop taking GLP-1s, they tend to regain most of that weight within a year, studies showed."[512]

593. Novo has publicly recognized that most individuals will regain all the weight back within five years of stopping Ozempic or Wegovy.[513] A trial published by Novo showed that after a year participants had gained back two thirds of the weight lost after they stopped taking semaglutide.[514] Indeed, Novo has acknowledged that some individuals will regain even more weight after stopping Ozempic or Wegovy than they initially lost.[515]

594. As noted by Novo's Martin Holst Lange: "once the majority of the weight loss is accrued, you don't go back and start to increase in weight ***if you stay on the drug***."[516]

595. Wegovy and Ozempic are often marketed as part of a "metabolic reset"[517] even though it knows that the weight will be regained upon cessation and even though it has recognized that GLP-1 RAs do not rewire "your neural networks to really define a new body weight setpoint."[518] Not only is it not a "reset," some patients will actually regain even more weight after

[512] Julie Stewart, *Help Patients Prevent Weight Gain After Stopping GLP-1s*, Medscape Med. News (Mar. 18, 2024), https://www.medscape.com/viewarticle/help-patients-prevent-weight-gain-after-stopping-glp-1s-2024a10004z9?form=fpf; *see also* https://www.medscape.com/viewarticle/help-patients-prevent-weight-gain-after-stopping-glp-1s-2024a10004z9?form=fpf.

[513] https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html.

[514] https://dom-pubs.onlinelibrary.wiley.com/doi/10.1111/dom.14725

[515] https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html.

[516] https://abcnews.go.com/GMA/Wellness/new-study-focuses-stay-weight-loss-drug-wegovy/story?id=110401021#:~:text=Were%20people%20able%20to%20keep%20weight%20off%20by,four%20years%20with%20continued%20use%20of%20the%20drug (emphasis added).

[517] https://www.joincalibrate.com/resources/how-long-does-it-take-to-lose-weight-on-ozempic.

[518] https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html.

stopping the drug.[519]

596. This was consistent with Lilly's sponsored SURMOUNT-4 study of tirzepatide, which showed that patients regained 14% of their body weight after switching from tirzepatide to a placebo.[520] On average, patients were able to maintain only about 10% of the weight lost from the time they started taking tirzepatide.[521] Notably, the trend towards weigh regain was on clear upward trajectory at the study endpoint, suggesting patients who had ceased taking the drug would continue to regain weight over time.

597. A meta-analysis of GLP-1 RA clinical trials found that "several GLP-1 RAs showed a gradual decline in effects on body weight throughout the long term intervention. In comparison to placebo, semaglutide resulted in a reduction of body weight from a mean difference of −3.28 kg (95% confidence interval −4.20 to −2.37) with medium term intervention to −2.75 kg (−4.60 to −0.89) with long term intervention. Liraglutide and dulaglutide also showed a similar trend."[522]

d. Not a Healthy Weight Loss

598. Taking GLP-1s may actually result in patients being less healthy. Defendants fully understand that overall health is more than a number, whether that number is purely weight or BMI. Despite this, the focus of prescribing GLP-1 RAs for obesity is on a person's BMI and to the extent that BMI is less than 30, whether they also have a weight-related health condition (*i.e.*,

[519] https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html.

[520] Arone et al, Continued Treatment With Tirzepatide for Maintenance of Weight Reduction in Adults With Obesity: the SURMOUNT-4 Randomized Clinical Trial, 331 JAMA 38 (2023).

[521] *Id.* at 45.

[522] Yao et al, Comparative effectiveness of GLP-1 receptor agonists on glycaemic control, body weight, and lipid profile for type 2 diabetes: systematic review and network meta-analysis, BMJ Open, 8 (2023).

cardiovascular disease, etc.).

599. As previously noted, BMI is a simple calculation that includes only weight and height. This poses limitations for its usefulness on an individual basis, rather than a population basis. For example, Jalen Hurts, Quarterback of the Philadelphia Eagles, is 6 feet and 1 inch tall and weighs 223 pounds, putting his BMI at 29.4 and making him extremely overweight and borderline obese if considering BMI alone. However, this does not account for the fact that he is an elite athlete with a body fat percentage under 10 percent. Nonetheless, if he suffers additional health condition or gains 5 pounds (or simply says he weighs 5 pounds more during a telehealth visit), he would qualify for one of the Defendants' weight loss drugs.

600. Because of these obvious limitations of BMI, the AMA has urged doctors to deemphasize their use of BMI in determining healthy weights for patients.[523] On June 14, 2023, the AMA adopted a new policy clarifying how BMI should be used as a measure in medicine.[524] The AMA suggests that BMI be used in conjunction with other valid measures of risk such as, but not limited to, measurements of visceral fat, body adiposity index, body composition, relative fat mass, waist circumference and genetic/metabolic factors.[525]

601. Weight loss as the sole indicator of health has also been rejected by many clinicians in favor of improvements in other health outcomes and the assess the whole health of an individual.[526] These clinicians have cautioned that "a lower body weight does not always mean a

[523] *Id*.

[524] https://www.ama-assn.org/press-center/press-releases/ama-adopts-new-policy-clarifying-role-bmi-measure-medicine (last visited Sept. 18, 2023).

[525] https://www.ama-assn.org/press-center/press-releases/ama-adopts-new-policy-clarifying-role-bmi-measure-medicine (last visited Sept. 18, 2023).

[526] https://link.springer.com/content/pdf/10.1007/s11606-022-07821-w.pdf?pdf=button (last visited on Sept. 18, 2023); https://newsroom.uw.edu/resource/why-body-mass-index-doesnt-give-whole-health-picture (last accessed Sept. 18, 2023).

person is healthier."[527] In many instances, when someone loses weight, they lose fat (a good result) but also lose muscle mass (bad).

602. It is recognized in the medical community that weight loss achieved by Ozempic and Wegovy is often a result of a significant loss of muscle mass.[528] As a result, individuals may be lighter than they were initially but have a higher percentage of body fat.[529]

603. To further exacerbate the problem, if patients stop taking a GLP-1 RA and regain weight, as discussed above, that weight gain is typically not adding muscle but instead adding fat. Therefore, the resulting "new you" is less healthy—weighing the same but having a higher percentage of body fat.

604. The loss of too much muscle mass can lead to sarcopenia, a condition called being "skinny fat," in which the patient has decreased muscle mass, lessened bone density, and lower resting metabolic rate—all of which results in a loss of strength and functionality.[530]

605. Lilly recognizes that much of the weight loss is actually healthy muscle tissue but rather than warn consumers that most of the weight loss on tirzepatide will be muscle loss, Lilly has instead invested in developing combination drugs to combat the muscle loss.[531]

606. Defendants did not warn about the dangers of the type of unhealthy weight loss occurring with GLP-1 RAs. Novo personnel refer to weight loss resulting from Wegovy is a

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[527] https://www.healthline.com/health-news/ozempic-muscle-mass-loss (last accessed Sept. 18, 2023).

[528] https://www.nbcnews.com/health/health-news/weight-loss-drugs-muscle-loss-rcna84936 (last accessed Sept. 18, 2023).

[529] https://www.afr.com/policy/health-and-education/lighter-but-fatter-the-ozempic-paradox-20230718-p5dp5w.

[530] https://www.healthline.com/health-news/ozempic-muscle-mass-loss (last accessed Sept. 18, 2023).

[531] https://www.nytimes.com/2024/02/08/well/live/ozempic-muscle-loss-exercise.html.

"healthy" weight loss.[532] At the same time, Novo told investors: "Healthy weight loss is, I don't want to call it the next frontier. But it is certainly important. . . . There is a risk if you do introduce very fast and dramatic weight loss you will lose almost 50-50 lean body mass and fat mass. So the tempered, but consistent body weight loss could potentially be healthier than a very dramatic fast weight loss."[533] Novo also stated that reasonable preservation of lean body mass "has to be a focus area, and you will probably see [it] in our pipeline."[534]

607. Similarly for Lilly, it was a "big investor question around [the] muscle issue"[535] and Lilly knew that "the quality of weight loss" mattered.[536] Lilly recognized that there could be some patients who "could benefit from both weight loss and maybe more muscle," hence why Lilly was investing in further research on products that would prevent muscle loss.[537]

608. Because Defendants do not warn of or disclose the type of weight loss occurring with GLP-1 RAs, patients do not factor that into their analysis of risks and benefits when considering taking a GLP-1 RA and are not aware that they should take specific steps to mitigate this muscle loss, like dietary changes and strength training.[538]

e. Many Patients Do Not Stay on the Drugs Long Enough to See Benefits

609. Approximately 58% of patients stop taking a GLP-1 RA within 12 weeks, and 30 percent stop in the first 4 weeks. In May of 2024, Blue Cross Blue Shield published "Real-World

[532] https://www.today.com/health/diet-fitness/is-wegovy-safe-for-weight-loss-rcna67277.

[533] *See* 2022-11-03 Q3 Earnings Call.

[534] *Id*.

[535] 20231128 Evercore ISI 6th Annual HealthCONx Conference.

[536] 2024430 Q1 2024 Earnings Call.

[537] 20231128 Evercore ISI 6th Annual HealthCONx Conference.

[538] https://www.afr.com/policy/health-and-education/lighter-but-fatter-the-ozempic-paradox-20230718-p5dp5w.

Trends in GLP-1 Treatment Persistence and Prescribing for Weight Management" noting these statistics.[539] This means that "[the] value [GLP-1 RA treatment] is not likely to be realized" in most patients.[540]

610. This is perhaps caused by the fact that side effects are most likely to present themselves in the first 12 weeks of use as the dosage increases. Lilly itself has noted that the risks of the medicine are often seen within just 12 weeks of use as patients are escalating the dosage up.[541] Physicians also recognize that adverse events are also more likely to occur during dose escalation with Ozempic and Wegovy.[542]

611. Neither Novo or Lilly warns or highlights that most people are unable to tolerate the drug and stay on it long enough for it to make a meaningful difference. These are clear indications that could impact a patient's decision to take a GLP-1 RA.

612. [redacted]

[539] May, 2024 Issue Brief on GLP1s.pdf, https://www.bcbs.com/media/pdf/BHI_Issue_Brief_GLP1_Trends.pdf (last accessed Oct. 17, 2024).

[540] Gleason *et al.*, *Real-world persistence and adherence to glucagon-like peptide-1 receptor agonists among obese commercially insured adults without diabetes*, 30 JMCP 2 (2024).

[541] https://www.washingtonpost.com/health/2023/08/08/weight-loss-drugs-side-effects-wegovy-ozempic/.

[542] https://www.braxtonmedicalclinic.com/post/understanding-the-side-effects-of-semaglutide-and-tirzepatide-a-comprehensive-guide-for-patients-of.

[543] [redacted]

[redacted]

EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

613. Defendants are estopped from relying on the statute of limitations defense because Defendants actively concealed information concerning known risks, side effects, and defects in the GLP-1 RAs. Instead of revealing such information to the FDA or the public, Defendants have continued to represent the GLP-1 RA products as safe for their intended use.

614. Defendants are and were under a continuing duty to disclose the true character, quality and nature of risks and dangers associated with their GLP-1 RA products. Because of

Defendants' purposeful and fraudulent concealment of material information concerning the true character, quality and nature of risks of such products, Defendants are estopped from relying on any statute of limitations defense.

CAUSES OF ACTION

COUNT I
FAILURE TO WARN - NEGLIGENCE
(AGAINST ALL DEFENDANTS)

615. Plaintiffs incorporate by reference each preceding and succeeding paragraph of the factual allegations as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of each Plaintiff's resident State.

616. Defendants had a duty to exercise reasonable care in designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, labeling, sale and/or distribution of their GLP-1 RA Products into the stream of commerce, including a duty to assure that the GLP-1 RA Products would not cause users to suffer unreasonable, dangerous side effects.

617. At all relevant times, Defendants failed to exercise ordinary care in the design, research, testing, manufacture, labeling, warnings, marketing, promotion, quality assurance, quality control, sale and/or distribution of their GLP-1 RA Products in that Defendants knew or should have known that the drugs could proximately cause Plaintiffs' injuries and/or presented an unreasonably high risk of injuries.

618. Defendants' GLP-1 RA Products were expected to and did reach the usual users and/or consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed, and marketed by Defendants.

619. At all relevant times, and at the times the GLP-1 RA Products left Defendants' control, Defendants knew or should have known that their GLP-1 RA Products were unreasonably dangerous because they did not adequately warn of the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

620. Despite the fact that Defendants knew or should have known that their GLP-1 RA Products caused unreasonably dangerous injuries, Defendants continued to market, distribute, and/or sell their GLP-1 RA Products to consumers, including Plaintiffs, without adequate warnings.

621. Despite the fact that Defendants knew or should have known that their GLP-1 RA Products caused unreasonably dangerous injuries, Defendants continued to market their GLP-1 RA Products to prescribing physicians, including Plaintiffs' prescribing physicians, without adequate warnings.

622. Defendants knew or should have known that consumers such as Plaintiffs would foreseeably suffer injuries as a result of their failure to provide adequate warnings, as set forth herein.

623. At all relevant times, given their increased safety risks, Defendants' GLP-1 RA Products were not fit for the ordinary purposes for which they were intended.

624. At all relevant times, given their increased safety risks, Defendants' GLP-1 RA Products did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiffs.

625. Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, labeling, sale and/or distribution of their GLP-1 RA Products into the stream of commerce, including a duty to assure that the products would not cause users to suffer unreasonable, dangerous injuries, such as malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated PE, gallbladder problems necessitating surgery, intraoperative aspiration, muscle wasting, vitamin deficiencies, malnutrition, dehydration, and their sequelae, including death.

626. At all relevant times, Plaintiffs were using Defendants' GLP-1 RA Products for the purposes and in a manner normally intended.

627. The GLP-1 RA Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate warnings or instructions, as Defendants knew or should have known that these products created a risk of serious and dangerous injuries, including the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle

wasting; dehydration and their sequelae, as well as other severe and debilitating personal injuries which are permanent and lasting in nature, and Defendants failed to adequately warn of said risks.

628. The GLP-1 RA Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects, including the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, as well as other severe, debilitating and permanent health consequences from their GLP-1 RA Products, they failed to provide adequate warnings to users and/or prescribers of these products, and continued to improperly advertise, market and/or promote their products.

629. At all relevant times, the labels for Defendants' GLP-1 RA Products were inadequate because they did not warn and/or adequately warn of all possible adverse side effects with reasonable evidence of a causal association involving GLP-1 RA Products, including the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting;

bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

630. At all relevant times, the labels for Defendants' GLP-1 RA Products were inadequate because they did not warn and/or adequately warn that their GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks, including the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

631. At all relevant times, the labels for Defendants' GLP-1 RA Products were inadequate because they did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of their GLP-1 RA Products.

632. At all relevant times, the labels for Defendants' GLP-1 RA Products were inadequate because they did not warn and/or adequately warn of the severity and duration of adverse effects, as the warnings given did not accurately reflect the symptoms or severity of the side effects.

633. Communications made by Defendants to Plaintiffs and Plaintiffs' prescribing physicians were inadequate because Defendants failed to warn and/or adequately warn of all

possible adverse side effects with reasonable evidence of a causal association with the use of their GLP-1 RA Products, including the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

634. Communications made by Defendants to Plaintiffs and Plaintiffs' prescribing physicians were inadequate because Defendants failed to warn and/or adequately warn that their GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks, including the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

635. Plaintiffs had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and Plaintiffs' reliance upon Defendants' warnings was reasonable.

636. Plaintiffs' prescribing physicians had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and Plaintiffs' prescribing physicians' reliance upon Defendants' warnings was reasonable.

637. Upon information and belief, had Plaintiffs' prescribing physicians been warned of the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, which have reasonable evidence of a causal association with Defendants' GLP-1 RA Products, then the prescribing physicians would not have prescribed Defendants' GLP-1 RA Products and/or would have provided Plaintiffs with adequate warnings regarding the dangers of Defendants' GLP-1 RA Products so as to allow Plaintiffs to make an informed decision regarding their use of Defendants' GLP-1 RA Products.

638. Upon information and belief, had Plaintiffs' prescribing physicians been warned that Defendants' GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks, including the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism;

gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, the prescribing physicians would not have prescribed Defendants' GLP-1 RA Products and/or would have provided Plaintiffs with adequate warnings regarding the lack of sufficient and/or adequate testing of Defendants' GLP-1 RA Products so as to allow Plaintiffs to make an informed decision regarding their use of Defendants' GLP-1 RA Products.

639. If Plaintiffs had been warned of the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, which have reasonable evidence of a causal association with Defendants' GLP-1 RA Products, then Plaintiffs would not have used Defendants' GLP-1 RA Products and/or suffered from gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

640. If Plaintiffs had been warned that Defendants' GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks, including the increased risks gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, then Plaintiffs would not have used Defendants' GLP-1 RA Products and/or suffered from gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

641. If Plaintiffs had been warned of the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury;

bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, which have reasonable evidence of a causal association with Defendants' GLP-1 RA Products, then Plaintiffs would have informed their prescribers that they did not want to take Defendants' GLP-1 RA Products.

642. Upon information and belief, if Plaintiffs had informed their prescribing physicians that they did not want to take Defendants' GLP-1 RA Products due to the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, or the lack of adequate testing for safety risks, then Plaintiffs' prescribing physicians would not have prescribed Defendants' GLP-1 RA Products.

643. By reason of the foregoing, Defendants have become liable to Plaintiffs for the designing, marketing, promoting, distribution and/or selling of their unreasonably dangerous GLP-RA Products.

644. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed defective products which created an unreasonable risk to the health of consumers and to Plaintiffs in particular, and Defendants are therefore liable for the injuries sustained by Plaintiffs.

645. Defendants' inadequate warnings for their GLP-1 RA Products were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

646. Said inadequate warnings for Defendants' GLP-1 RA Products were a substantial factor in causing Plaintiffs' injuries.

647. Plaintiffs intend to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

648. As a direct and proximate result of one or more of the foregoing acts and omissions, Plaintiffs were caused to suffer serious and dangerous injuries, including gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

649. As a direct and proximate result of one or more of the foregoing acts and omissions, Plaintiffs also suffered consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages. Plaintiffs are

informed and believe and further allege that they will require future medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, medical monitoring to diagnose GLP-1 RA induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II
FAILURE TO WARN – STRICT LIABILITY
(AGAINST ALL DEFENDANTS)

650. Plaintiffs incorporate by reference each preceding and succeeding paragraph of the factual allegations as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of each Plaintiff's resident State.

651. State law, including the states in which Plaintiffs live, imposes a duty on producers, manufacturers, distributors, lessors, and sellers of a product to exercise all reasonable care when designing, researching, manufacturing, producing, distributing, leasing, and selling their products.

652. At all relevant times, Defendants designed, researched, manufactured, produced, tested, advertised, promoted, marketed, sold, and/or distributed the GLP-1 RA Products that Plaintiffs used.

653. Defendants' GLP-1 RA Products were expected to and did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed, and marketed by Defendants.

654. At all relevant times, and at the times Defendants' GLP-1 RA Products left Defendants' control, Defendants knew or should have known that their GLP-1 RA Products were

unreasonably dangerous because they did not adequately warn of the risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, especially when used in the form and manner as provided by Defendants.

655. Despite the fact that Defendants knew or should have known that their GLP-1 RA Products had reasonable evidence of a causal association with unreasonably dangerous injuries, Defendants continued to market, distribute, and/or sell their GLP-1 RA Products to consumers, including Plaintiffs, without adequate warnings.

656. Despite the fact that Defendants knew or should have known that their GLP-1 RA Products had reasonable evidence of a causal association with unreasonably dangerous injuries, Defendants continued to market their GLP-1 RA Products to prescribing physicians, including Plaintiffs' prescribing physicians, without adequate warnings.

657. Defendants knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury as a result of their failure to provide adequate warnings, as set forth herein.

658. At all relevant times, given their increased safety risks, Defendants' GLP-1 RA Products were not fit for the ordinary purposes for which they were intended.

659. At all relevant times, given their increased safety risks, Defendants' GLP-1 RA Products did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiffs.

660. Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, labeling, sale, and/or distribution of their GLP-1 RA Products into the stream of commerce, including a duty to assure that the products would not cause users to suffer unreasonable, dangerous injuries, such as gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

661. At all relevant times, Plaintiffs were using Defendants' GLP-1 RA Products for the purposes and in a manner normally intended.

662. The GLP-1 RA Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate warnings or instructions, as Defendants knew or should have known that these products created a risk of serious and dangerous injuries, including gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and

associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, as well as other severe and debilitating personal injuries which are permanent and lasting in nature, and Defendants failed to adequately warn of said risks.

663. At all relevant times, the labels for Defendants' GLP-1 RA Products were inadequate because they did not warn and/or adequately warn of all possible adverse side effects which have reasonable evidence of a causal association with the use of the GLP-1 RA Products, including the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

664. At all relevant times, the labels for Defendants' GLP-1 RA Products were inadequate because they did not warn and/or adequately warn that the GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks, including the increased risks gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery;

esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

665. At all relevant times, the labels for Defendants' GLP-1 RA Products were inadequate because they did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of the GLP-1 RA Products.

666. At all relevant times, the labels for Defendants' GLP-1 RA Products were inadequate because they did not warn and/or adequately warn of the severity and duration of adverse effects, as the warnings given did not accurately reflect the symptoms or severity of the side effects.

667. Communications made by Defendants to Plaintiffs and Plaintiffs' prescribing physicians were inadequate because Defendants failed to warn and/or adequately warn of all possible adverse side effects with reasonable evidence of a causal association with the use of their GLP-1 RA Products, including the increased gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

668. Communications made by Defendants to Plaintiffs and Plaintiffs' prescribing physicians were inadequate because Defendants failed to warn and/or adequately warn that their GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks, including

the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

669. Plaintiffs had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and Plaintiffs' reliance upon Defendants' warnings was reasonable.

670. Plaintiffs' prescribing physicians had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and Plaintiffs' prescribing physicians' reliance upon Defendants' warnings was reasonable.

671. Upon information and belief, had Plaintiffs' prescribing physicians been warned of the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, which have reasonable evidence of a causal association with Defendants' GLP-1 RA Products, then the prescribing physicians would not have prescribed Defendants' GLP-1 RA

Products, and/or would have provided Plaintiffs with adequate warnings regarding the dangers of Defendants' GLP-1 RA Products, so as to allow Plaintiffs to make an informed decision regarding their use of Defendants' GLP-1 RA Products.

672. Upon information and belief, had Plaintiffs' prescribing physicians been warned that Defendants' GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks, including the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, the prescribing physicians would not have prescribed Defendants' GLP-1 RA Products, and/or would have provided Plaintiffs with adequate warnings regarding the lack of sufficient and/or adequate testing of Defendants' GLP-1 RA Products, so as to allow Plaintiffs to make an informed decision regarding their use of Defendants' GLP-1 RA Products.

673. If Plaintiffs had been warned of the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle

wasting; dehydration and their sequelae, which have reasonable evidence of a causal association with Defendants' GLP-1 RA Products, then Plaintiffs would not have used Defendants' GLP-1 RA Products, and/or suffered from gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

674. If Plaintiffs had been warned that Defendants' GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks, including the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, then Plaintiffs would not have used Defendants' GLP-1 RA Products and/or suffered from gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting;

bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

675. If Plaintiffs had been warned of the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, which have reasonable evidence of a causal association with Defendants' GLP-1 RA Products, then Plaintiffs would have informed Plaintiffs' prescribing physicians that they did not want to use Defendants' GLP-1 RA Products.

676. Upon information and belief, if Plaintiffs had informed their prescribing physicians that they did not want to use Defendants' GLP-1 RA Products due to the risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle

wasting; dehydration and their sequelae., or the lack of adequate testing for safety risks, then Plaintiffs' prescribing physicians would not have prescribed Defendants' GLP-1 RA Products.

677. By reason of the foregoing, Defendants have become liable to Plaintiffs for the designing, marketing, promoting, distribution and/or selling of Defendants' unreasonably dangerous GLP-1 RA Products.

678. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed defective products which created an unreasonable risk to the health of consumers and to Plaintiffs in particular, and Defendants are therefore liable for the injuries sustained by Plaintiffs.

679. Defendants' inadequate warnings for their GLP-1 RA Products were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

680. Said inadequate warnings for Defendants' GLP-1 RA Products were a substantial factor in causing Plaintiffs' injuries.

681. Plaintiffs intend to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

682. As a direct and proximate result of one or more of the foregoing acts and omissions, Plaintiffs were caused to suffer serious and dangerous injuries, including gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury;

bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

683. As a direct and proximate result of one or more of the foregoing acts and omissions, Plaintiffs also suffered consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages. Plaintiffs are informed and believe and further allege that they will require future medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, medical monitoring to diagnose GLP-1 RA induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III
BREACH OF EXPRESS WARRANTY / FAILURE TO CONFORM TO REPRESENTATIONS (AGAINST ALL DEFENDANTS)

684. Plaintiffs incorporate by reference each preceding and succeeding paragraph of the factual allegations as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of each Plaintiff's resident State.

685. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the GLP-1 RA Products that Plaintiffs used.

686. At all relevant times, Defendants expressly represented to Plaintiffs and Plaintiffs' prescribing physicians that their GLP-1 RA Products were safe as an adjunct to diet and exercise to improve glycemic control and to reduce cardiovascular risks in adults with type 2 diabetes mellitus, and/or to aid in chronic weight management.

687. The aforementioned express representations were made to Plaintiffs and Plaintiffs' prescribing physicians by way of Defendants' GLP-1 RA Products' labels, websites, advertisements, promotional materials, and through other statements.

688. As a result of Defendants' express representations, Plaintiffs' prescribing physicians were induced to prescribe Defendants' GLP-1 RA Products to Plaintiffs, and Plaintiffs were induced to use Defendants' GLP-1 RA Products.

689. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as Plaintiffs, would use and/or consume their GLP-1 RA Products based upon their express representations.

690. At all relevant times, Defendants reasonably anticipated and expected that prescribing physicians, such as Plaintiffs' prescribing physicians, would recommend, prescribe and/or dispense Defendants' GLP-1 RA Products based upon their express representations.

691. At all relevant times, Defendants knew or should have known that their GLP-1 RA Products were unreasonably dangerous because of their increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury;

bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, especially when the drugs were used in the form and manner as provided by Defendants.

692. At all relevant times, Defendants knew or should have known that their GLP-1 RA Products had not been sufficiently and/or adequately tested for safety.

693. The unreasonably dangerous characteristics of Defendants' GLP-1 RA Products were beyond that which would be contemplated by the ordinary user, such as Plaintiffs, with the ordinary knowledge common to the public as to the drugs' characteristics.

694. The unreasonably dangerous characteristics of Defendants' GLP-1 RA Products were beyond that which would be contemplated by Plaintiffs' prescribing physicians, with the ordinary knowledge common to prescribing physicians as to the drugs' characteristics.

695. At the time Defendants' GLP-1 RA Products left Defendants' control, the GLP-1 RA Products did not conform to Defendants' express representations because the GLP-1 RA Products were not safe to use as an adjunct to diet and exercise to improve glycemic control and to reduce cardiovascular risks in adults with type 2 diabetes, and/or to aid in chronic weight management, in that the drugs have reasonable evidence of a causal association with increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative

aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

696. The express representations made by Defendants regarding the safety of their GLP-1 RA Products were made with the intent to induce Plaintiffs to use the products and/or Plaintiffs' prescribing physicians to prescribe the products.

697. Defendants knew and/or should have known that by making the express representations to Plaintiffs and/or Plaintiffs' prescribing physicians, it would be the natural tendency of Plaintiffs to use Defendants' GLP-1 RA Products and/or the natural tendency of Plaintiffs' prescribing physicians to prescribe Defendants' GLP-1 RA Products.

698. Plaintiffs and Plaintiffs' prescribing physicians, as well as members of the medical community, relied on the express representations of Defendants identified herein.

699. Had Defendants not made these express representations, Plaintiffs would not have used Defendants' GLP-1 RA Products and/or, upon information and belief, Plaintiffs' prescribing physicians would have altered their prescribing practices and/or would have provided Plaintiffs with adequate warnings regarding the dangers of Defendants' GLP-1 RA Products so as to allow Plaintiffs to make an informed decision regarding their use of Defendants' GLP-1 RA Products.

700. Had Plaintiffs been warned of the increased risks which have reasonable evidence of a causal association with Defendants' GLP-1 RA Products, Plaintiff would not have used Defendants' GLP-1 RA Products and and/or suffered from gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and

associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

701. Had Plaintiffs been warned that Defendants' GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks, including gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, Plaintiff would not have used Defendants' GLP-1 RA Products and/or suffered gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

702. Accordingly, Defendants are liable as a result of their breach of express warranties to Plaintiffs.

703. Defendants' breaches of express warranties were a substantial factor in causing Plaintiffs' injuries.

704. Plaintiffs' injuries and damages arose from a reasonably anticipated use of Defendants' GLP-1 RA Products by Plaintiffs.

705. Plaintiffs intend to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

706. As a direct and proximate result of one or more of the foregoing breaches, Plaintiffs were caused to suffer serious and dangerous injuries including gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, as well as other severe and debilitating personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

707. As a direct and proximate result of one or more of the foregoing breaches, Plaintiffs also suffered consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages. Plaintiffs are informed

and believe and further allege that they will require future medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, medical monitoring to diagnose GLP-1 RA induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV
BREACH OF IMPLIED WARRANTY
(AGAINST ALL DEFENDANTS)

708. Plaintiffs incorporate by reference each preceding and succeeding paragraph of the factual allegations as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of each Plaintiff's resident State.

709. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the GLP-1 RA Products that Plaintiffs used.

710. Defendants' GLP-1 RA Products were expected to and did reach the usual consumers, handlers, and persons encountering said products without substantial change in the condition in which they were produced, manufactured, sold, distributed, and marketed by the Defendants.

711. At all relevant times, Defendants impliedly warranted to Plaintiffs, Plaintiffs' prescribing physicians, and the medical community that Defendants' GLP-1 RA Products were of merchantable quality and safe and fit for their ordinary purposes.

712. At all relevant times, Defendants knew or should have known that their GLP-1 RA Products were unreasonably dangerous because of their increased risks of gastroparesis;

gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, especially when the drugs were used in the form and manner as provided by Defendants.

713. At all relevant times, Defendants knew or should have known that their GLP-1 RA Products had not been sufficiently and/or adequately tested for safety.

714. At the time Defendants' GLP-1 RA Products left Defendants' control, the GLP-1 RA Products did not conform to Defendants' implied warranties and were unfit for their ordinary purposes because Defendants failed to provide adequate warnings of the drugs' causal association with increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

715. At all relevant times, Defendants reasonably anticipated and expected that prescribing physicians, such as Plaintiffs' prescribing physicians, would recommend, prescribe

and/or dispense Defendants' GLP-1 RA Products for use by their patients to improve glycemic control in adults with type 2 diabetes, to reduce cardiovascular risk, and/or to aid in chronic weight management.

716. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as Plaintiffs, would use and/or consume Defendants' GLP-1 RA Products for their ordinary purposes.

717. Despite the fact that Defendants knew or should have known that their GLP-1 RA Products cause unreasonably dangerous injuries, such as gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, Defendants continued to market, distribute, and/or sell their GLP-1 RA Products to consumers, including Plaintiffs, without adequate warnings.

718. The unreasonably dangerous characteristics of Defendants' GLP-1 RA Products were beyond that which would be contemplated by the ordinary user, such as Plaintiffs, with the ordinary knowledge common to the public as to the drugs' characteristics.

719. The unreasonably dangerous characteristics of Defendants' GLP-1 RA Products were beyond that which would be contemplated by Plaintiffs' prescribing physicians, with the ordinary knowledge common to prescribing physician as to the drugs' characteristics.

720. Plaintiffs reasonably relied on Defendants' implied warranties of merchantability relating to their GLP-1 Products' safety and efficacy.

721. Plaintiffs reasonably relied upon Defendants' skill and judgment as to whether their GLP-1 RA Products were of merchantable quality and safe and fit for their intended uses.

722. Upon information and belief, Plaintiffs' prescribing physicians relied on Defendants' implied warranties of merchantability and fitness for the ordinary use and purpose relating to their GLP-1 RA Products.

723. Upon information and belief, Plaintiffs' prescribing physicians, reasonably relied upon the skill and judgment of Defendants as to whether their GLP-1 RA Products were of merchantable quality and safe and fit for their intended use.

724. Had Defendants not made these implied warranties, Plaintiffs would not have used Defendants' GLP-1 RA Products, and/or, upon information and belief, Plaintiffs' prescribing physicians would not have prescribed Defendants' GLP-1 RA Products, and/or would have altered their prescribing practices and/or would have provided Plaintiffs with adequate warnings regarding the dangers of Defendants' GLP-1 RA Products, to allow Plaintiffs to make an informed decision regarding their use of Defendants' GLP-1 RA Products.

725. Defendants herein breached the aforesaid implied warranties of merchantability because their GLP-1 RA Products were not fit for their intended purposes.

726. Defendants' breaches of implied warranties of merchantability were a substantial factor in causing Plaintiffs' injuries.

727. Plaintiffs intend to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

728. As a direct and proximate result of one or more of the foregoing breaches, Plaintiffs were caused to suffer serious and dangerous injuries including gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

729. As a direct and proximate result of one or more of the foregoing breaches, Plaintiffs also suffered consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages. Plaintiffs are informed and believe and further allege that they will require future medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, medical monitoring to diagnose GLP-1 RA induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V
FRAUDULENT CONCEALMENT/FRAUD BY OMISSION
(AGAINST ALL DEFENDANTS)

730. Plaintiffs incorporate by reference each preceding and succeeding paragraph of the factual allegations as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of each Plaintiff's resident State.

731. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed GLP-1 RA Products, which were used by Plaintiffs as hereinabove described.

732. At all relevant times, Defendants knew or should have known that their GLP-1 RA Products had not been adequately and/or sufficiently tested for safety.

733. At all relevant times, Defendants knew or should have known that their GLP-1 RA Products were unreasonably dangerous because of the increased risk of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae., especially when the drug was used in the form and manner as provided by Defendants.

734. Defendants had a duty to disclose material information about their GLP-1 RA Products to Plaintiffs and Plaintiffs' prescribing physicians, namely that the GLP-1 RA Products have reasonable evidence of a causal association with increased risk of gastroparesis; gastroparesis

requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae., because Defendants have superior knowledge of the drugs and their dangerous side effects, this material information is not readily available to Plaintiff or Plaintiffs' prescribing physicians by reasonable inquiry, and Defendants knew or should have known that Plaintiff and Plaintiffs' prescribing physicians would act on the basis of mistaken knowledge.

735. Nonetheless, Defendants consciously and deliberately withheld and concealed from Plaintiffs' prescribing physicians, Plaintiffs, the medical and healthcare community, and the general public this material information.

736. Defendants' promotional websites for GLP-1 RA Products similarly do not disclose that there is reasonable evidence of a causal association between GLP-1 RA Products and increased risk of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative

aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae..

737. Defendants' omissions and concealment of material facts were made purposefully, willfully, wantonly, and/or recklessly in order to mislead and induce medical and healthcare providers, such as Plaintiffs' prescribing physicians, and patients, such as Plaintiffs, to dispense, provide, prescribe, accept, purchase, and/or consume GLP-1 RA Products.

738. Defendants knew or should have known that Plaintiffs' prescribing physicians, and Plaintiffs would rely on Defendants' omissions and prescribe or use GLP-1 RA Products because they were unaware of the risks of serious side effects, gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

739. Defendants knew that Plaintiffs and Plaintiffs' prescribing physicians had no way to uncover the concealed information and determine the truth surrounding GLP-1 RA Products, as set forth herein.

740. Upon information and belief, Plaintiffs' prescribing physicians justifiably relied on Defendants' material omissions when making the decision to dispense, provide, and prescribe GLP-1 RA Products.

741. Upon information and belief, had Plaintiffs' prescribing physicians been warned of the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, with reasonable evidence of a causal association with GLP-1 RA Products, they would not have prescribed GLP-1 RA Products and/or would have provided Plaintiffs with adequate information regarding the increased risk of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae associated with GLP-1 RA Products to allow Plaintiffs to make an informed decision regarding Plaintiffs' use of GLP-1 RA Products.

742. Upon information and belief, had Plaintiffs' prescribing physicians been told that GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks, including gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy;

gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, they would not have prescribed GLP-1 RA Products and/or would have provided Plaintiffs with adequate warnings regarding the lack of sufficient and/or adequate testing of GLP-1 RA Products to allow Plaintiffs to make an informed decision regarding Plaintiffs' use of GLP-1 RA Products.

743. Plaintiffs justifiably relied on Defendants' missions when making the decision to purchase and/or consume GLP-1 RA Products.

744. Had Plaintiffs been informed of the increased risks with reasonable evidence of a causal association with GLP-1 RA Products, Plaintiffs would not have used GLP-1 RA Products and/or suffered injuries including gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

745. Defendants' fraudulent concealments were a substantial factor in causing Plaintiffs' injuries.

746. Plaintiffs intend to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

747. As a direct or proximate result of Defendants' fraudulent concealment and omissions, Plaintiffs were caused to suffer serious and dangerous injuries, which resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

748. Defendants' fraudulent concealment and omissions, Plaintiffs suffered bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, medical monitoring to diagnose GLP-1 RA induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI
FRAUDULENT / INTENTIONAL MISREPRESENTATION
(AGAINST ALL DEFENDANTS)

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[544] Plaintiffs reserve the right to amend to add fraud claims after discovery.

COUNT VII
UNFAIR TRADE PRACTICES / CONSUMER PROTECTION
(AGAINST ALL DEFENDANTS)

749. Plaintiffs incorporate by reference each preceding and succeeding paragraph of the factual allegations as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of each Plaintiff's resident State. Plaintiffs plead this Cause of Action under all applicable product liability acts, statutes, and laws of each Plaintiff's respective resident State.

750. At all relevant times, all Defendants named herein designed, manufactured, assembled, inspected, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed the GLP-1 RA Products into the stream of commerce, and therefore owed not only a duty of reasonable care to avoid causing harm to those that consumed it, such as Plaintiffs, but also separate and independent statutory duties to be truthful, fair, accurate, and to not mislead or deceive consumers in connection with the sale of GLP-1 RA Products, under the laws of each State in which GLP-1 RA Products were sold.

751. Defendants engaged in unfair competition or unfair, deceptive, misleading, false, fraudulent, or unconscionable acts or practices in violation of the state and territory consumer protection statutes listed below when they misled consumers regarding the safety risks associated with use of their GLP-1 RA Products, by overstating benefits and understating risks from using the products, and by marketing the products for uses for which the products were not approved, as described in more detail above. As a direct result of such unfair, deceptive, misleading, false, fraudulent, or unconscionable acts or practices by Defendants, Plaintiffs suffered and will continue to suffer economic loss, pecuniary loss, personal injury, loss of consortium, companionship and society, mental anguish, and/or other compensable injuries.

752. Certain Plaintiffs herein will bring a cause of action for consumer fraud and/or unfair and deceptive trade practices under applicable state law.

753. Defendants are on notice that such claims may be asserted by those Plaintiffs.

754. Plaintiffs purchased and/or used one or more GLP-1 RA Product(s) and suffered injuries and direct economic loss as a result of Defendants' actions in violation of these consumer protection laws.

755. Had Defendants not engaged in the deceptive conduct described herein, Plaintiffs would not have purchased or used a GLP-1 RA Product and would not have suffered their resulting physical injuries and economic losses as alleged herein.

756. Fraudulent, unfair, and/or deceptive practices that violate consumer protection laws include but are not limited to the following:

a. representing that goods or services have approval, characteristics, uses, or benefits that they do not have;

b. advertising goods or service with the intent not to sell them as advertised; and

c. engaging in fraudulent or deceptive conduct that creates a likelihood of confusion.

757. Plaintiffs were injured by Defendants' unlawful conduct, which was intended to through a pervasive pattern of false and misleading statements and omissions about GLP-1 RA Products by overstating benefits, marketing the products off label, and by omitting or downplaying side effects, complications and adverse events from the information provided about the GLP-1 RA Products to physicians and to consumers.

758. Defendants have a statutory duty to refrain from fraudulent, unfair, and deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of their products. Defendants' deceptive, unconscionable, unfair and/or fraudulent representations and

material omissions to Plaintiffs constituted consumer fraud and/or unfair and deceptive acts and trade practices in violation of consumer protection statutes, including, but not limited to, the following:

a. Ala. Ala. Code § 8-19-1 *et seq.*;

b. Alaska Stat. § 45.50.471 *et seq.*;

c. Ariz. Rev. Stat. Ann. § 44-1521 *et seq.*;

d. Ark. Code Ann. § 4-88-101 *et seq.*;

e. Cal. Civ. Code § 1750 *et seq.* and Cal. Bus. & Prof. Code § 17200 *et seq.*;

f. Colo. Rev. Stat. § 6-1-101 *et seq.*;

g. Conn. Gen. Stat. § 42-110a *et seq.*;

h. Del. Code Ann. tit. 6, § 2511 *et seq.*, § 2531 *et seq.*;

i. D.C. Code Ann. § 28-3901 *et seq.*;

j. Fla. Stat. Ann. § 501.201 *et seq.*;

k. Ga. Code Ann. § 10-1-370 *et seq.*;

l. Haw. Rev. Stat. § 480-1 *et seq.* and 481A-1 *et seq.*;

m. Idaho Code Ann. § 48-601 *et seq.*;

n. 815 Ill. Comp. Stat. Ann. 505/1 *et seq.*;

o. Ind. Code Ann. § 24-5-0.5-1 *et seq.*;

p. Iowa Code Ann. § 714.16 *et seq.*;

q. Kan. Stat. Ann. § 50-623, *et seq.*;

r. Ky. Rev. Stat. Ann. § 367.110 *et seq.*;

s. La. Rev. Stat. Ann. § 51:1401 *et seq.*;

t. Me. Rev. Stat. Ann. tit. 5, § 205-A *et seq.*;

u. Md. Code Ann., Com. Law § 13-101 *et seq.*;

v. Mass. Gen. Laws Ann. Ch. 93A, § 1 *et seq.*;

w. Mich. Comp. Laws §§ 445.901 *et seq.*;

x. Minn. Stat. §§ 325D.09 *et seq.*, 325D.43, *et seq.*, 325F.67 *et seq.*, 325F.68, 325F.69 and § 8.31;

y. Miss. Code Ann. § 75-24-3 *et seq.*;

z. Mo. Ann. Stat. § 407.010 *et seq.*;

aa. Mont. Code Ann. § 30-14-101 *et seq.*;

bb. Neb. Rev. Stat. § 87-301 *et seq.*;

cc. Nev. Rev. Stat. § 598.0903 *et seq.* and § 41.600;

dd. N.H. Rev. Stat. Ann. § 358-A:1 *et seq.*;

ee. N.J. Stat. Ann. § 56:8-1 *et seq.*;

ff. N.M. Stat. Ann. § 57-12-1 *et seq.*;

gg. N.Y. Gen. Bus. Law §§ 349 *et seq.*, 350, 350-a and 350-e *et seq.*;

hh. N.C. Gen. Stat. § 75-1.1 *et seq.*;

ii. N.D. Cent. Code § 51-12-01 *et seq.*, §§ 51-15-01 *et seq.*;

jj. Ohio Rev. Code Ann. § 1345.01 *et seq.*;

kk. Okla. Stat. Ann. tit. 15 § 751 *et seq.*;

ll. Or. Rev. Stat. § 646.605 *et seq.*;

mm. 73 Pa. Cons. Stat. § 201-1 *et seq.*;

nn. R.I. Gen. Laws. § 6-13.1-1 *et seq.*;

oo. S.C. Code Ann. § 39-5-10 *et seq.*;

pp. S.D. Codified Laws § 37-24-1 *et seq.*;

qq. Tenn. Code Ann. § 47-18-101 *et seq.*;

rr. Tex. Bus. & Com. Code Ann. § 17.41 *et seq.*;

ss. Utah Code Ann. § 13-11-1 *et seq.*;

tt. Vt. Stat. Ann. tit. 9, § 2451 *et seq.*;

uu. Va. Code Ann. § 59.1-196 *et seq.*;

vv. Wash. Rev. Code. § 19.86.010 *et seq.*;

ww. W. Va. Code § 46A-6-101 *et seq.*;

xx. Wis. Stat. Ann. § 100.18 *et seq.* and 421.101 *et seq.*;

yy. Wyo. Stat. Ann. §§ 40-12-101 *et seq.*; and

zz. American Samoa Code Ann. § 27.0401 *et seq.*;

aaa. 4 CMC § 5101 *et seq.*;

bbb. 5 Guam Code Ann. § 32102 *et seq.*;

ccc. 12A Virgin Is. Code § 301 *et seq.*

759. Under these and other consumer protection statutes, Defendants are the suppliers, distributors, manufacturers, advertisers, marketers, promoters and sellers of GLP-1 RA Products, who are subject to liability under such legislation from fraudulent, unfair, deceptive, and unconscionable consumer sales practices.

760. The actions and omissions of Defendants are uncured or incurable, or, Defendants had actual notice or were put on adequate notice by Plaintiffs of these acts or omissions and these claims arising from such acts and omissions sufficient to satisfy any statutory notice requirements.

761. Plaintiffs relied to their detriment on Defendants' misrepresentations and omissions about the GLP-1 RA Products in deciding to purchase and use GLP-1 RA Products, and Plaintiffs' prescribing physicians relied to Plaintiffs' detriment on Defendants' misrepresentations and omissions about the GLP-1 RA Products in communicating with Plaintiffs about the products and in deciding to prescribe GLP-1 RA Products to Plaintiffs.

762. Plaintiffs at all times acted as reasonable consumers in relying upon Defendants' misrepresentations and material omissions of risks and safety information concerning Defendants' GLP-1 Products in choosing to purchase and consume the GLP-1 RA Products prescribed to them by their physicians.

763. Plaintiffs intend to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

764. By reason of the unlawful acts engaged in by Defendants in violation of the above-cited laws, and as a direct and proximate result thereof, Plaintiffs have sustained ascertainable loss and damages, serious injuries, economic and non-economic losses and other damages and are entitled to statutory and compensatory damages as permitted by applicable law.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, medical monitoring to diagnose GLP-1 RA-induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII
NEGLIGENT MISREPRESENTATION / MARKETING
(AGAINST ALL DEFENDANTS)

765. Plaintiffs incorporate by reference each preceding and succeeding paragraph of the factual allegations as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of each Plaintiff's resident State.

766. At all relevant times, Defendants negligently provided Plaintiff, Plaintiffs' prescribing physicians, the general medical community, and the public with false, fraudulent, and/or incorrect information or omitted or failed to disclose material information concerning GLP-1 RA Products, including, but not limited to, misrepresentations and marketing regarding the safety and known risks of GLP-1 RA Products.

767. At all relevant times, Defendants negligently provided Plaintiffs, Plaintiffs prescribing physicians, the general medical community, and the public with false, fraudulent,

and/or incorrect information or omitted or failed to disclose material information concerning GLP-1 RA Products, including, but not limited to, misrepresentations and marketing regarding the long-term effects of GLP-1 RA Products.

768. The information distributed by Defendants to the public, the medical community, Plaintiffs and Plaintiffs' prescribing physicians, including advertising campaigns, labeling materials, print advertisements, commercial media, and marketing was false and misleading and contained omissions and concealment of truth about the dangers of GLP-1 RA Products.

769. Defendants' conduct had the capacity to deceive and/or its purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiffs and Plaintiffs' health care providers; to falsely assure them of the quality of GLP-1 RA Products and induce the public and medical community, including Plaintiffs and Plaintiffs' prescribing physicians to request, recommend, purchase, and prescribe GLP-1 RA Products.

770. Defendants had a duty to accurately and truthfully represent and market to the medical and healthcare community, medical pharmaceutical manufacturers, Plaintiffs, Plaintiffs' prescribing physicians and the public, the known risks of GLP-1 RA Products, including its propensity to cause gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

771. Defendants made continued omissions in the GLP-1 RA Products labeling, including promoting it as safe and effective while failing to warn of its propensity to cause gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

772. Defendants made additional misrepresentations beyond the product labeling by representing GLP-1 RA Products as a safe and effective treatment for diabetes with only minimal risks.

773. Defendants misrepresented and overstated the benefits of GLP-1 RA Products to Plaintiffs, Plaintiffs' prescribing physicians, and the medical community without properly advising of the known risks to patients.

774. Defendants made the misrepresentations alleged herein with the intent to induce consumers, like Plaintiffs, to take their diabetes treatment product.

775. In reliance upon the false, deceptive and negligent misrepresentations and omissions and marketing made by Defendants, Plaintiffs and Plaintiffs' healthcare providers were induced to, and did use and prescribe GLP-1 RA Products, and relied upon the affirmative misrepresentations and/or negligent omissions in doing so.

776. As a direct and proximate result of the foregoing negligent misrepresentations and marketing and conduct with capacity to deceive and/or intention to deceive, Plaintiffs suffered serious and ongoing injuries.

777. As a direct and proximate result of the foregoing misrepresentations, marketing, and deceitful intentions, Plaintiffs require and/or will require more healthcare and services and did incur medical, health, incidental, and related expenses.

778. Defendants knew or should have known that Plaintiffs, Plaintiffs' prescribing prescribing physicians, and the general medical community did not have the ability to determine the true material facts which were intentionally and/or negligently concealed and misrepresented by Defendants.

779. Plaintiffs and Plaintiffs' prescribing physicians would not have used or prescribed GLP-1 RA Products had the true facts not been concealed by Defendants.

780. Defendants had sole access to many of the material facts concerning the defective nature of GLP-1 RA Products and its propensity to cause serious and dangerous side effects.

781. At the time Plaintiffs were prescribed and administered GLP-1 RA Products, Plaintiffs and Plaintiffs prescribing physicians were unaware of Defendants' negligent misrepresentations and omissions.

782. Defendants failed to exercise ordinary care in making representations concerning GLP-1 RA Products while they were involved in the manufacture, design, sale, testing, quality assurance, quality control, promotion, marketing, labeling, and distribution in interstate commerce, because Defendants negligently misrepresented high risk of unreasonable and dangerous adverse side effects their GLP-1 RA Products.

783. Plaintiffs and Plaintiffs' prescribing physicians reasonably relied upon the misrepresentations and omissions made by Defendants, where they concealed and misrepresented facts that were critical to understanding the true and full dangers inherent in the use of the GLP-1 RA Products.

784. Plaintiffs and Plaintiffs' prescribing physicians reliance on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiffs' injuries.

785. Plaintiffs intend to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

786. As a direct or proximate result of Defendants negligent acts described herein, Plaintiffs were caused to suffer serious and dangerous injuries, which resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

787. As a direct and proximate result of Defendants negligent acts described herein, Plaintiffs suffered bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, medical monitoring to diagnose GLP-1 RA induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper

COUNT IX
STRICT PRODUCT LIABILITY MISREPRESENTATION / MARKETING
(AGAINST ALL DEFENDANTS)

788. Plaintiffs incorporate by reference each preceding and succeeding paragraph of the factual allegations as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of each Plaintiff's resident State.

789. State law, including the states in which Plaintiffs live, imposes a duty on producers, manufacturers, distributors, lessors, and sellers of a product to exercise all reasonable care when marketing, promoting, distributing, and selling their products.

790. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the GLP-1 RA Products which were used by Plaintiffs as hereinabove described.

791. Defendants made material misrepresentations to Plaintiffs, Plaintiffs' prescribing physicians, the medical and healthcare community at large, and the general public regarding the safety and/or efficacy of their GLP-1 RA Products.

792. Defendants represented affirmatively and by omission on advertisements and on the labels of their GLP-1 RA Products that their GLP-1 RA Products were safe and effective drugs for treatment of adults with type 2 diabetes, to aid in chronic weight management, and to reduce cardiac risk, despite the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury;

bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, conditions with reasonable evidence of a causal association with GLP-1 RA Products.

793. Defendants' representations were false or misleading and/or concealed and/or omitting material information from Plaintiffs, Plaintiffs' prescribing physicians, the medical and healthcare community, and the general public.

794. Plaintiffs and Plaintiffs' prescribing physicians had no way to determine the truth behind Defendants' misrepresentations and concealments surrounding their GLP-1 RA Products, as set forth herein.

795. Upon information and belief, Plaintiffs' prescribing physicians justifiably relied on Defendants' material misrepresentations, including the omissions contained therein, when making the decision to prescribe Defendants' GLP-1 RA Products to Plaintiffs.

796. Upon information and belief, had Plaintiffs' prescribing physicians been warned of the increased risks gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, which have reasonable evidence of a causal association with Defendants' GLP-1 RA Products, Plaintiffs' prescribing physicians would not have prescribed Defendants' GLP-1 RA Products and/or would have provided Plaintiffs with adequate information regarding the safety of

Defendants' GLP-1 RA Products to allow Plaintiffs to make an informed decision regarding their use of Defendants' GLP-1 RA Products.

797. Upon information and belief, had Plaintiffs' prescribing physicians been told that Defendants' GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks, including gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, they would not have prescribed Defendants' GLP-1 RA Products and/or would have provided Plaintiffs with adequate warnings regarding the lack of sufficient and/or adequate testing of Defendants' GLP-1 RA Products so that Plaintiffs could make an informed decision regarding their use of Defendants' GLP-1 RA Products.

798. Plaintiffs reasonably relied on the false and/or misleading facts and information disseminated by Defendants, which included Defendants' omissions of material facts in which Plaintiffs had no way to know were omitted.

799. Plaintiffs intend to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

800. Had Plaintiffs been told of the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to

debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, which have reasonable evidence of a causal association with Defendants' GLP-1 RA Products, Plaintiffs would not have used Defendants' GLP-1 RA Products and/or suffered from gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

801. As a direct and proximate result of one or more the foregoing false representations and/or omissions, Plaintiffs were caused to suffer serious and dangerous injuries including gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic

bowel; muscle wasting; dehydration and their sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

802. As a direct and proximate result of one or more of the foregoing false representations and/or omissions, Plaintiffs have also suffered consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages. Plaintiffs are informed and believe and further allege that they will require future medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, medical monitoring to diagnose GLP-1 RA induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT X
INNOCENT MISREPRESENTATION / MARKETING
(AGAINST ALL DEFENDANTS)

803. Plaintiffs incorporate by reference each preceding and succeeding paragraph of the factual allegations as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of each Plaintiff's resident State.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, medical monitoring to diagnose GLP-1 RA induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XI
NEGLIGENT DESIGN
(AGAINST ALL DEFENDANTS)

804. Plaintiffs incorporate by reference each preceding and succeeding paragraph of the factual allegations as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of each Plaintiff's resident State.

805. Defendants are liable to Plaintiffs for the injuries and damages sustained due to Defendants' negligent design and/or formulation of their GLP-1 RA Products.

806. At all relevant times, Defendants owed a duty to consumers including Plaintiffs and their health care providers, to assess, manage, and communicate the risks, dangers, and adverse effects of their GLP-1 RA Products. Defendants' duties included, but were not limited to, carefully and properly designing, testing, studying, and manufacturing their GLP-1 RA Products.

807. Defendants negligently and carelessly breached the above-described duties to Plaintiffs by, among other acts and omissions, negligently and carelessly:

a. Failing to use ordinary care in designing, testing, and manufacturing their GLP-1 RA Products;

b. Failing to design their GLP-1 RA Products as to properly minimize the adverse effects to the gastrointestinal and immune systems;

c. Failing to counteract in the design the known adverse effects on the gastrointestinal and immune systems;

d. Designing products where the benefits were greatly outweighed by the risks including malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated PE, gallbladder problems necessitating surgery, intraoperative aspiration, muscle wasting, vitamin deficiencies, malnutrition, dehydration, and their sequelae, including death; and

e. Designing products without taking into consideration the proper dosage that could avoid malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated PE, gallbladder

> problems necessitating surgery, intraoperative aspiration, muscle wasting, vitamin deficiencies, malnutrition, dehydration, and their sequelae, including death.

808. Defendants' GLP-1 RA Products were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design or formulation.

809. At all relevant times, given their lack of efficacy and increased safety risks, Defendants' GLP-1 RA Products did not meet the reasonable expectations of an ordinary consumer, particularly the Plaintiffs, or in the alternative, Plaintiffs' medical providers.

810. Defendants' GLP-1 RA Products were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers and/or distributors, they were unreasonably dangerous, more dangerous than an ordinary consumer would expect, and more dangerous than other similar drugs.

811. Despite Defendants' knowledge of the foreseeable risks and unreasonably dangerous nature of their GLP-1 RA Products, at all relevant times, Defendants designed and brought the products to market and continued to market the drugs when there were safer alternatives available, including but not limited to alternate dosing and reduced exposure.

812. Plaintiffs intend to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

813. As a direct and proximate result of one or more of the foregoing negligent acts and omissions by Defendants, Plaintiffs were caused to suffer serious and dangerous injuries including gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C,

D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

814. As a direct and proximate result of one or more of the foregoing negligent acts and omissions by Defendants, Plaintiffs have also suffered consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages. Plaintiffs are informed and believe and further allege that they will require future medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, medical monitoring to diagnose GLP-1 RA induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XII
STRICT LIABILITY DESIGN DEFECT
(AGAINST ALL DEFENDANTS)

815. Plaintiffs incorporate by reference each preceding and succeeding paragraph of the factual allegations as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of each Plaintiff's resident State.

816. Plaintiffs are in the class of persons that Defendants should reasonably foresee as being subject to the harm caused by defectively designed GLP-1 RA Products insofar as Plaintiffs were the type of persons for whom the GLP-1 RA Products were intended to be used.

817. At all times mentioned herein, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed the GLP-1 RA Products that were used by Plaintiffs.

818. Defendants, who are engaged in the business of designing, researching, manufacturing, testing, advertising, promoting, marketing, selling and/or distributing the GLP-1 RA Products that were used by Plaintiffs, placed them into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the GLP-1 RA Products.

819. The GLP-1 RA Products supplied to Plaintiffs were defective in design or formulation and unreasonably dangerous when they left the hands of Defendants, and they reached the users and consumers of the products, including Plaintiffs, without substantial alteration in the condition in which they were sold.

820. Defendants' GLP-1 RA Products were defective in design or formulation in that:

a. Defendants knew or should have known of the dangers associated with their GLP-1 RA Products, but failed to use ordinary care in designing, researching, manufacturing, testing, advertising, promoting, marketing, selling and/or distributing their GLP-1 RA Products;

b. The benefits of Defendants' GLP-1 RA Products were greatly outweighed by the foreseeable risks associated with the design or formulation of their GLP-1 RA Products including gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury;

intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae;

c. There was a safer, economically feasible alternative design or formulation for Defendants' GLP-1 RA Products that Defendants could have used;

d. The design or formulation of Defendants' GLP-1 RA Products failed to properly minimize the known adverse effects to the gastrointestinal and immune systems;

e. The design or formulation of Defendants' GLP-1 RA Products failed to counteract the known adverse effects on the gastrointestinal and immune systems; and

f. The design or formulation of Defendants' GLP-1 RA Products failed to take into consideration the proper dosage that could avoid malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated PE, gallbladder problems necessitating surgery, intraoperative aspiration, muscle wasting, vitamin deficiencies, malnutrition, dehydration, and their sequelae, including death.

821. At all relevant times, given their lack of efficacy and increased safety risks, Defendants' GLP-1 RA Products did not meet the reasonable expectations of an ordinary consumer, particularly the Plaintiffs, or in the alternative, Plaintiffs' prescribing physicians.

822. Defendants' GLP-1 RA Products were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers and/or distributors, they were unreasonably dangerous, more dangerous than an ordinary consumer would expect, and more dangerous than other similar drugs.

823. Despite Defendants' knowledge of the foreseeable risks and unreasonably dangerous nature of their GLP-1 RA Products, at all relevant times, Defendants designed and brought the products to market and continued to market the drugs when there were safer alternatives available, including but not limited to alternate dosing and reduced exposure.

824. Plaintiffs intend to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

825. As a direct and proximate result of one or more of the foregoing acts and omissions by Defendants, Plaintiffs were caused to suffer serious and dangerous injuries including gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

826. As a direct and proximate result of one or more of the foregoing acts and omissions by Defendants, Plaintiffs have also suffered consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages. Plaintiffs are informed and believe and further allege that they will require future medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, medical monitoring to diagnose GLP-1 RA induced injuries at an earlier

date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XIII
NEGLIGENCE
(AGAINST ALL DEFENDANTS)

827. Plaintiffs incorporate by reference each preceding and succeeding paragraph of the factual allegations as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of each Plaintiff's resident State.

828. Defendants, directly or indirectly, caused their GLP-1 RA Products to be sold, distributed, packaged, labeled, marketed, promoted, and used by Plaintiffs. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, overpromoted, and sold their GLP-1 RA Products throughout the United States.

829. At all relevant times, Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, labeling, sale and/or distribution of their GLP-1 RA Products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that did not cause users to suffer from unreasonable, dangerous side effects without an adequate warning—when used alone or in foreseeable combination with other drugs.

830. At all relevant times, Defendants knew, or in the exercise of reasonable care, should have known of the hazards and dangers associated with their GLP-1 RA Products, and specifically that use of these drugs could cause gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting;

bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

831. At all relevant times, Defendants knew, or in the exercise of reasonable care, should have known that the use of their GLP-1 RA Products could cause Plaintiffs' injuries, and thus, created a dangerous and unreasonable risk of injury to the users of these products that Defendants did not warn of.

832. Defendants knew, or in the exercise of reasonable care, should have known that users and consumers were unaware of the risks and magnitude of the risks associated with the use of their GLP-1 RA Products.

833. Defendants breached their duty of care to Plaintiffs and Plaintiffs' treating physicians, in the warning, testing, monitoring, and pharmacovigilance of their GLP-1 RA Products.

834. In disregard of their duties, Defendants committed one or more of the following negligent acts or omissions:

a. Manufacturing, producing, overpromoting, marketing, formulating, creating, developing, designing, selling, and distributing their GLP-1 RA Products, without thorough and adequate pre- and post-market testing of the products;

b. Manufacturing, producing, overpromoting, marketing, advertising, formulating, creating, developing, and distributing their GLP-1 RA Products, and upon information and belief, while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risks of serious harm associated with the use of their GLP-1 RA Products;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not their GLP-1 RA Products were safe for their intended uses;

d. Upon information and belief, failing to disclose and warn of the products' defects to the regulatory agencies, the medical community, and consumers that

Defendants knew and had reason to know that their GLP-1 RA Products were indeed unreasonably unsafe and unfit for use by reason of the products' defects and risks of harm to their users;

e. Failing to warn Plaintiffs, the medical and healthcare community, and consumers that their GLP-1 RA Products' risks of harm were unreasonable and that there were safer and effective alternative products available to Plaintiffs and other consumers;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would use their GLP-1 RA Products;

g. Advertising, marketing, and recommending the use of their GLP-1 RA Products, while concealing and failing to disclose or warn of the dangers Defendants knew or should have known to be connected with, and inherent in, the use of their GLP-1 RA Products;

h. Representing that their GLP-1 RA Products were safe for weight management when in fact Defendants knew and/or should have known the products were not safe for that purpose;

i. Continuing to manufacture and sell their GLP-1 RA Products with the knowledge that their GLP-1 RA Products, when used for weight management, were unreasonably unsafe and dangerous;

j. Failing to use reasonable and prudent care in the design, research, testing, manufacture, and development of their GLP-1 RA Products so as to avoid the risks of serious harm associated with the use of their GLP-1 RA Products. Failing to design and manufacture their GLP-1 RA Products so as to ensure the drugs were at least as safe and effective as other similar products;

k. Failing to ensure that their GLP-1 RA Products were accompanied by proper and accurate warnings about the increased risks of gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae;

l. Failing to ensure that their GLP-1 RA Products were accompanied by proper and accurate warnings about possible adverse side effects associated with the use of their GLP-1 RA Products and that use of their GLP-1 RA Products created a high risk of severe and debilitating injuries; and

m. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of their GLP-1 RA Products.

835. A reasonable manufacturer, designer, distributor, promoter, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

836. As a direct and proximate result of Defendants' negligent testing, monitoring, and pharmacovigilance of their GLP-1 RA Products, Defendants introduced drugs into every State where Plaintiffs reside which they knew or should have known would cause serious, severe and debilitating injuries, including gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae.

837. The aforementioned negligence and wrongs done by Defendants were aggravated by the kind of grossly negligent conduct and disregard for the rights of others, the public, and Plaintiffs, for which the law allows the imposition of exemplary or punitive damages, in that Defendants' conduct involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants proceeded with a reckless disregard to the rights, safety, and welfare of others, including Plaintiffs.

838. Defendants are liable in tort to Plaintiffs for their wrongful conduct pursuant to law of the State in which each Plaintiff resides.

839. Plaintiffs intend to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

840. As a direct or proximate result of one or more of the foregoing negligent acts and omissions, Plaintiffs were caused to suffer serious and dangerous injuries, which resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

841. As a direct and proximate result of one or more of the foregoing negligent acts and omissions by Defendants, Plaintiffs suffered bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, medical monitoring to diagnose GLP-1 RA induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XIV
NEGLIGENT UNDERTAKING
(AGAINST ALL DEFENDANTS)

842. Plaintiffs incorporate by reference each preceding and succeeding paragraph of the factual allegations as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of each Plaintiff's resident State.

843. Numerous state laws recognize liability related to the voluntary assumption of a duty or undertaking. This includes the voluntary undertaking of targeting patients with direct-to-consumer marketing campaigns.

844. Defendants voluntarily undertook the responsibility to market their GLP-1 RAs directly to the consumer instead of solely to physicians and other health care providers. In choosing to target the ordinary consumer with their DTC marketing campaigns, the Defendants undertook the responsibility to do so in truthful and non-misleading manner and to adequately warn of the risks of their products. Having undertaken the responsibility, Defendants are required to do so with reasonable care.

845. Courts have recognized that DTC advertising "provides the consumer with a diluted variation of risks associated with the drug product" and "[c]onsumers often interpret such warnings as a 'general reassurance' that their condition can be treated," rather than an awareness of risks. *See, e.g, Perez v. Wyeth Lab'ys Inc.*, 161 N.J. 1, 14, 734 A.2d 1245, 1253 (1999).

846. Some states recognize that the learned intermediary doctrine doesn't apply when the patient uses the drug as a result of DTC marketing. This is consistent with Novo's own statement to investors discussing the marketing launch of Wegovy: "With regards to patients, before the launch of Wegovy, we saw that patients were in doubt, is there a help to get? Should I just exercise more and eat less? Is that all I can do? They were used to that message from physicians. ***But now we know that the obesity market is driven by people showing up at the physician's office and a big, big part of the prescriptions are driven by patients asking for more help***."[545]

[545] 2024-03-07 Capital Markets Day.

847. The FDA requires pharmaceutical promotional materials to be truthful and non-misleading and that they comply with applicable statutory and regulatory requirements. The FDA looks not just at specific risk-related statements, but at the net impression of promotional materials.

848. Common law requires a company to act with reasonable care when they assume a duty to the consumer.

849. As alleged above, Defendants failed to warn consumers in their DTC advertisements about the true nature and extent of the risks associated with their GLP-1 RAs. This includes warnings as to gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, and the true efficacy of the drugs – primarily that most patients stop taking the drugs and regain any weight that was lost. Only a small percentage of patients ever reach a normal BMI on weight loss drugs.

850. Instead, Defendants advertisements promoted happy images of individuals stating they would "lose weight and keep it off." This DTC campaign amassed over 13 million impressions in the first 3 days after launch.

851. Another campaign by Novo for Wegovy promoted up to "46 pounds" of weight loss. Another actor stated that in regards to weight loss, "I'm keeping it off." Yet, this vastly overstates the benefits for Wegovy. As Novo told investors at its 2024 Capital Markets Day, less

than 1 in 10 weight loss patients sustained the weight loss for four years. The mean weight loss at 4 years for semaglutide is 10.2%. In order to achieve a 35 pound weight loss, a patient must – on average – start at a weight of 350 pounds. Only 12 percent of individuals achieved a BMI of less than 25 – which is considered the upper limit for a normal BMI.

852. Novo also does not disclose in its DTC marketing campaigns that the majority of patients stop taking its weight loss drugs in the first year. Novo has, however, told investors that only 32% of patients on Wegovy remained after one year and that this was partly due to a lack of "tolerability."

853. One study found that only 24.1% of Wegovy patients persisted in continuous treatment for 2 years. Novo recognizes that many patients stop taking its weight loss drugs due to adverse events or intolerability.

854. Research has also shown that within a year of stopping the weight loss drug, patients have regained two-thirds of their prior weight loss. Novo has stated that patients who stop using weight loss drugs risk regaining all the weight back within five years.

855. Novo does not disclose the need to remain on its weight loss drugs forever in order to maintain weight loss in its direct-to-consumer marketing campaigns. Nor does Novo disclose that everyone is at risk of regaining all the weight back within five years.

856. Lilly also advertises Zepbound to help "lose weight and keep it off." Studies show, however, that when patients stop taking Zepbound they gain most of the weight back within a year. Lilly does not disclose this in their direct-to-consumer marketing campaigns.

857. If this information had been disclosed to Plaintiffs, then they would not have sought a prescription for the Defendants' weight loss drugs.

858. As a direct and proximate result of Defendant's breach of duty of care, Plaintiffs suffered mental and physical injuries from taking Defendants' GLP-1 RAs.

859. Defendants are liable in tort to Plaintiffs for their wrongful conduct pursuant to law of the State in which each Plaintiff resides.

860. Plaintiffs intend to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

861. As a direct and proximate result of one or more of the foregoing acts and omissions by Defendants, Plaintiffs were caused to suffer serious and dangerous injuries including gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; DVT and associated pulmonary embolism; gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; acute necrotizing pancreatitis; ischemic bowel; muscle wasting; dehydration and their sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

862. As a direct and proximate result of these negligent acts and omissions by Defendants, Plaintiffs suffered bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, medical monitoring to diagnose GLP-1 RA induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XV
WRONGFUL DEATH
(AGAINST ALL DEFENDANTS)

863. Plaintiffs incorporate by reference each preceding and succeeding paragraph of the factual allegations as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of each Plaintiff's resident State.

864. Certain Plaintiffs-Decedents have suffered and incurred a premature and untimely death as a direct and proximate result of the wrongful conduct of the Defendants enumerated above.

865. At all relevant times, certain Plaintiffs-Decedents were married to spouses or had children who are recognized as individuals entitled to bring a claim for compensation due to the death of the Decedent under the applicable state's wrongful death statute or common law.

866. The wrongful conduct of the Defendants enumerated above caused or contributed to cause the death of Plaintiffs-Decedents.

867. The wrongful conduct of Defendants enumerated above was a proximate cause of the death of Plaintiffs-Decedents.

868. Plaintiffs-Decedents intends to plead all claims of product liability that are supported by the factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

869. As alleged throughout this Master Long Form Complaint and as incorporated herein, Defendants are liable for Plaintiffs-Decedents' suffering and death, for each Plaintiff-Decedent's survivors' damages, for damages sustained by Plaintiffs-Decedents' estate, and for all other injuries and damages flowing from Plaintiffs-Decedents' death.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XVI
LOSS OF CONSORTIUM
(AGAINST ALL DEFENDANTS)

870. Plaintiffs incorporate by reference each preceding and succeeding paragraph of the factual allegations as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of each Plaintiff's resident State.

871. At all relevant times, certain Plaintiffs were married to spouses or had minor children.

872. Plaintiffs intend to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

873. As a direct and proximate result of the injuries and damages sustained by certain Plaintiffs, their spouses, loved ones, and minor children have suffered the loss of services, care, comfort, society, and affection (conjugal or otherwise) from Plaintiffs.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XVII
SURVIVAL ACTION
(AGAINST ALL DEFENDANTS)

874. Plaintiffs incorporate by reference each preceding and succeeding paragraph of the factual allegations as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of each Plaintiff's resident State.

875. The legal estate of certain Plaintiffs-Decedents is entitled to pursue a survival claim on behalf of the Plaintiff-Decedents under applicable state law.

876. Plaintiffs-Decedents intend to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

877. As alleged throughout this Master Long Form Complaint and as incorporated herein, Defendants are liable for Plaintiffs-Decedents' suffering and death, for each Plaintiff-Decedent's survivors' damages, for damages sustained by Plaintiff-Decedent's estate, and for all other injuries and damages flowing from Plaintiff-Decedent's death.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants on each of the above referenced claims and causes of action, jointly and severally, as follows:

(a) Awarding compensatory damages in excess of $75,000, including, but not limited to pain, suffering, discomfort, physical impairment, emotional distress, loss of enjoyment of life, loss

of consortium, wrongful death and other noneconomic damages in an amount to be determined at trial of this action;

(b) Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determined at trial of this action;

(c) Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

(d) Pre-judgment interest;

(e) Post-judgment interest;

(f) medical monitoring to diagnose GLP-1 RA induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries;

(g) Awarding reasonable attorneys' fees;

(h) Awarding the costs of these proceedings; and

(i) Such other and further relief as this Court deems just and proper.

JURY DEMAND

TAKE NOTE that Plaintiffs demand trial by jury as to all issues herein.

Dated: November 12, 2024

RESPECTFULLY SUBMITTED,

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